



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee met on April 19, 2006. The following up are action items and comments from the meeting. Minutes from the meeting are located after copies of the 2005 Watch Bills.

1. Board Sponsored Legislation Update

AB 595 (Negrete McLeod) Pharmacy: compounding of prescription drugs.

Status: Senate Floor.

This bill is sponsored by the board to establish standards for pharmacies that compound and to provide direction for regulations that will follow later this year. The board approved this legislative proposal at its January 2005 meeting.

AB 2408 (Negrete McLeod) Pharmacists, pharmacies, and nonresident pharmacies.

Status: Status: Assembly Appropriations Committee.

This bill is sponsored by the board and would update the definition of a pharmacy, nonresident pharmacy, and the professional practice of pharmacy. The board approved draft legislation at its February 2006 meeting.

Steve Gray, representing Kaiser Permanente, had a number of questions regarding this bill. One item the committee directed for board discussion at this meeting is whether the policy outlined in AB 2408 conforms to board recommendations adopted at the January Board Meeting regarding Licensing Committee recommendations for regulating pharmacists who provide services to Californians from outside California.

In section 4051(c), if a pharmacist outside California provides cognitive services to Californians in this state, the pharmacist either needs to be licensed by California as a pharmacist, or work/be associated with a nonresident pharmacy that is licensed in California.

SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill.

Status: Senate Business, Professions And Economic Development Committee – Hearing April 24, 2006.

The board approved eight proposals for the omnibus legislation, however only three of the eight proposals are currently in the bill.

Approved Proposals in SB 1475

B&P 4104 Licensed Employee, Theft, Impairment: Pharmacy Procedures.

B&P 4162 Wholesalers Surety Bond Requirements.

B&P 4180-4182 and 4190-4192 Nonprofit or Free Clinics.

Approved Proposals NOT in SB 1475

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment.

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device.

B&P 4160 Wholesaler License.

B&P 4127.1 Injectable Sterile Drug Products.

B&P 4073 Substitution of Generic Drug, Check off Box on Electronic Prescriptions.

Addition to the Omnibus Bill: A request from MedImmune, Inc. to amend B&P § 4162.5(a)(4) related to surety bond requirements. On March 21, 2006 the board received a letter from Colleen Chawla, Government Affairs Manager for MedImmune, Inc.. MedImmune Inc. is requesting the board sponsor legislation for a technical amendment to B&P Section 4162.5(a)(4), Submission of Surety Bond for the Issuance or Renewal of Nonresident Wholesaler License; Exemption. A copy of the letter from MedImmune Inc. and proposed language follows the copy of the Omnibus bill in this section.

SB 1476 (Figueroa) Board Sunset Extension Bill.

Status: Senate Business, Professions And Economic Development Committee – Hearing April 24, 2006

Note: The board needs to support this bill.

This bill will extend the board's sunset date two years, from 2008 to 2010. The board's sunset report to the Legislature will be due September 2008. Additionally the measure would repeal B&P section 4163.5, effectively moving the implementation date of electronic pedigree requirement from January 1, 2007 to January 1, 2008.

2. 2006 Bills of Interest

AB 2198 (Houston) Health care: controlled substances and dangerous drugs.

Status: Assembly Health Committee.

Committee Recommendation: None.

AB 2308 (Plescia) Ambulatory surgical centers: licensure.

Status: Assembly Health Committee - Hearing April 25, 2006.

Committee Recommendation: None.

AB 2583 (Nation) Dispensing prescription drugs and devices: refusal to dispense.

Status: Assembly Appropriations Committee.

Committee Recommendation: Oppose Unless Amended.

Proposed Amendments: (1) Specify in law the exact wording of the sign. (2) Require pharmacies, rather than the board, to print the sign. (3) Why is the sign needed if the point it for patients to get their medications due to protocol in B&P 733 (b)(3)(A)?

AB 2743 (Matthews) Pharmacists: ancillary personnel.

Status: Assembly Business and Professions Committee – Hearing April 25, 2006.

Committee Recommendation: No Position.

AB 2986 (Mullin) Controlled substances: prescription requirements.

Status: Assembly Public Safety Committee - Hearing April 18, 2006.

Committee Recommendation: No Position.

SB 1366 (Aanestad) Controlled substances.

Status: Assembly Public Safety Committee - Hearing April 25, 2006.

Committee Recommendation: Neutral.

3. 2006 Watch Bills

AB 1908 (Karnette) Medi-Cal: pharmacy reimbursement.

Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2057 (Cogdill) Controlled substances.

Status: Assembly Appropriations Committee.

AB 2373 (Plescia) Automated drug delivery system.

Status: Assembly Business and Professions Committee.

AB 2730 (Nation) Medi-Cal: contract drug list: advertising.

Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2856 (Hancock) Informed consent: prescription medication off-label use.

Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2877 (Frommer) Prescription drugs: importation: procurement.

Status: Assembly Business and Professions Committee.

AB 2911 (Nunez) California Discount Prescription Drug Program.

Status: Assembly Health Committee - Hearing April 25, 2006.

AJR 40 (Chan) Medicare Prescription Drugs.

Status: Senate.

AJR 49 (Nation) Direct-To-Consumer Prescription Drug Advertisements

Status: Assembly Health Committee - Hearing May 2, 2006.

SB 1305 (Figueroa) The Medical Waste Management Act.

Status: Senate Environmental Quality Committee – Hearing April 24, 2006.

SB 1430 (Alquist) The Local Pandemic and Emergency Health Preparedness Act of 2006.

Status: Senate Floor.

SB 1683 (Scott) Pharmaceutical information: clinical trial data.

Status: Senate Health Committee – Hearing April 25, 2006.

4. 2005 Watch Bills

AB 651 (Berg) California Compassionate Choices Act.

Status: Senate Rules Committee.

This bill would enact the California Compassionate Choices Act, which would authorize an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease to make a request for medication for the purpose of ending his or her life in a humane and dignified manner. The bill would establish procedures for making these requests.

Note: The following list of bills is included for your information. The board does not have a position on any of these bills and most are likely inactive or dead. Copies of the bills can be found on the Internet at <http://www.leginfo.ca.gov/bilinfo.html>.

AB 21 (Levine) Pharmacists: contraceptive devices.

Status: Senate Health Committee - Hearing Cancelled.

AB 71 (Chan) Pharmaceuticals: adverse drug reactions: Office of Ca. Drug Safety Watch.

Status: Senate Health Committee - Hearing Cancelled.

AB 75 (Frommer) Pharmaceutical assistance program.

Status: Senate Health Committee - Hearing Cancelled.

AB 225 (Negrete McLeod) Electronic prescription information.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 283 (Koretz) Pseudoephedrine: retail sale.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 657 (Karnette) Pharmacies: prescription containers.

Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

SB 380 (Alquist) Drugs: adverse event reporting.

Status: Assembly Floor, failed passage. Reconsideration granted. Inactive file.

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.

Status: Assembly Health Committee - Failed passage in committee. Reconsideration granted.

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*Board Sponsored
Legislation*

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AMENDED IN SENATE MAY 26, 2005
AMENDED IN ASSEMBLY APRIL 18, 2005
AMENDED IN ASSEMBLY MARCH 29, 2005
CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including "manufacturer."

This bill would delete the definition of manufacturer. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard. Because the bill would specify requirements for compounded drug products under the Pharmacy Law, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4019.5 is added to the Business and
2 Professions Code, to read:

3 4019.5. (a) "Compounding" means any of the following
4 activities occurring in a pharmacy pursuant to a prescription:

5 (1) Altering the dosage form or delivery system of a drug.

6 (2) Altering the strength of a drug.

7 (3) Combining components or active ingredients.

8 (4) Preparing a drug product from bulk chemicals.

9 (b) "Compounding" shall not include the reconstitution of a
10 drug pursuant to the manufacturer's direction for oral, rectal, or
11 topical administration.

12 ~~(c) This section shall not apply to over-the-counter drugs or~~
13 ~~nonprescription drugs.~~

14 SEC. 2. Section 4033 of the Business and Professions Code is
15 repealed.

16 SEC. 3. Section 4051 of the Business and Professions Code is
17 amended to read:

18 4051. (a) Except as otherwise provided in this chapter, it is
19 unlawful for any person to compound, furnish, sell, or dispense
20 any dangerous drug or dangerous device, or to dispense or
21 compound any prescription pursuant to Section 4040 of a
22 prescriber unless he or she is a pharmacist under this chapter.

23 (b) Notwithstanding any other law, a pharmacist may
24 authorize the initiation of a prescription, pursuant to Section
25 4052, and otherwise provide clinical advice or information or
26 patient consultation if all of the following conditions are met:

27 (1) The clinical advice or information or patient consultation is
28 provided to a health care professional or to a patient.

29 (2) The pharmacist has access to prescription, patient profile,
30 or other relevant medical information for purposes of patient and
31 clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~(g) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the
4 penalty for a crime or infraction, within the meaning of Section
5 17556 of the Government Code, or changes the definition of a
6 crime within the meaning of Section 6 of Article XIII B of the
7 California Constitution.

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AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2408

Introduced by Assembly Member ~~Calderon~~ *Negrete McLeod*

February 23, 2006

~~An act to amend Section 10153.4 of, to amend, repeal, and add Sections 10156.6, 10156.7, and 10215 of, to add and repeal Section 10153.10 of, and to repeal Section 10154 of, the Business and Professions Code, relating to real estate salespersons. An act to amend Sections 4036, 4037, 4050, 4051, 4052, 4112, 4120, 4201, 4207, 4301, and 4306.5 of, to amend, renumber, and add Section 4052.1 of, to add Sections 4052.2 and 4052.3 to, and to repeal and add Section 4302 of, the Business and Professions Code, relating to pharmacies.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 2408, as amended, ~~Calderon~~ *Negrete McLeod*. ~~Real estate salespersons; conditional licensure. Pharmacies.~~

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacies by the Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime.

Existing law defines a pharmacist and a pharmacy, requires pharmacists and pharmacies to be licensed by the board, and authorizes a licensee to engage in certain activities. Existing law also sets forth activities that constitute unprofessional conduct for a pharmacist to engage in.

This bill would require a pharmacist to be a natural person, and would entitle a licensed pharmacist to practice pharmacy within or outside of a licensed pharmacy. The bill would revise the activities in

which a pharmacist may engage, including the adjustment of prescriptions and provisions of cognitive services, would revise the pharmacist's responsibilities and requirements with regard to certain activities, and would make certain additional acts or omissions unprofessional conduct. The bill would revise the definition of a pharmacy to include, among other things, all pharmacies in which the profession of pharmacy is practiced. The bill would list different types of pharmacies and would require a pharmacy or nonresident pharmacy to specify its type in its application for licensure and to update the board if that information changes. The bill would make it unlawful for an unlicensed person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other health care providers.

Existing law defines a nonresident pharmacy and requires a nonresident pharmacy to meet certain criteria, including registration with the board. Existing law prohibits an unregistered nonresident pharmacy from engaging in certain activities, including selling or distributing dangerous drugs or dangerous devices in this state through any person or media other than a licensed wholesaler. Existing law requires a nonresident pharmacy to disclose to the board the location, names, and titles of specified persons, including all pharmacists dispensing controlled substances, dangerous drugs, or dangerous devices to residents of California. Existing law authorizes the board to deny, revoke, or suspend a nonresident registration for failure to comply with specified requirements or for conduct that causes serious bodily or psychological injury to a California resident, in specified circumstances.

This bill would revise the definition of a nonresident pharmacy to require shipping, mailing, or delivering directly to patients in California, and to include a pharmacy located outside of the state that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. The bill would delete the requirement that a nonresident pharmacy must disclose the location, names, and titles of pharmacists, and the prohibition against a nonresident pharmacy selling or distributing dangerous drugs or devices in California through any person or media other than a licensed wholesaler. This bill would also delete the authorization for the board to deny, revoke, or suspend a nonresident registration for

failure to comply with specified requirements or for conduct causing serious bodily harm or psychological injury to a California resident, and would instead authorize the board to deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment, or take any other action against a nonresident pharmacy that it may take against a resident pharmacy. The bill would also authorize the board to report violations of laws or regulations by a nonresident pharmacy to its regulatory or licensing agency.

This bill would revise and recast related provisions of the Pharmacy Law.

Because this bill would create new requirements and prohibitions under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~Existing law, the Real Estate Law, provides for the licensure and regulation of real estate salespersons by the Department of Real Estate. Under that law, an applicant for licensure as a real estate salesperson is required to submit to the Real Estate Commissioner evidence of the successful completion of specified courses in real estate either prior to issuance of the license or within 18 months after its issuance.~~

~~This bill would, for persons who apply for licensure on or after January 1, 2007, delete the provisions from the Real Estate Law that allow an applicant to submit evidence of his or her completion of the real estate courses within 18 months after issuance of the license.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4036 of the Business and Professions
- 2 Code is amended to read:
- 3 4036. "Pharmacist" means a *natural* person to whom a
- 4 license has been issued by the board, under Section 4200, except

1 as specifically provided otherwise in this chapter. *The holder of*
2 *an unexpired and active pharmacist license issued by the board*
3 *is entitled to practice pharmacy as defined by this chapter, within*
4 *or outside of a licensed pharmacy as authorized by this chapter.*

5 *SEC. 2. Section 4037 of the Business and Professions Code is*
6 *amended to read:*

7 4037. (a) "Pharmacy" means an area, place, or premises
8 licensed by the board in which the profession of pharmacy is
9 practiced ~~and where prescriptions are compounded~~. Only a
10 "dispensing pharmacy," as defined in subdivision (b), may
11 possess, prepare, manufacture, derive, compound, repackage,
12 furnish, sell, or dispense controlled substances, dangerous drugs,
13 or dangerous devices. In all other respects, whenever the term
14 "pharmacy" is used in this chapter, it shall be deemed to refer to
15 all of the types of pharmacies listed in subdivision (b).

16 ~~"Pharmacy"~~

17 (b) "Pharmacy" includes, but is not limited to, ~~any~~ all of the
18 following:

19 (1) A "dispensing pharmacy," which is any area, place, or
20 premises described in a license issued by the board wherein
21 controlled substances, dangerous drugs, or dangerous devices are
22 stored, possessed, prepared, manufactured, derived, compounded,
23 or repackaged, and from which the controlled substances,
24 dangerous drugs, or dangerous devices are furnished, sold, or
25 dispensed at retail.

26 ~~(b)~~

27 (2) A "prescription processing pharmacy," which is any area,
28 place, or premises described in a license issued by the board
29 wherein personnel licensed by the board engage in or supervise
30 drug order or prescription review by performing functions
31 including, but not limited to, data entry, drug utilization review,
32 patient or prescriber contact, patient profile review, and allergy
33 and drug-interaction review.

34 (3) An "advice/clinical center pharmacy," which is any area,
35 place, or premises described in a license issued by the board
36 wherein personnel licensed by the board provide cognitive
37 pharmacy services including, but not limited to, clinical advice
38 or information, telephonic or in-person patient consultation,
39 drug utilization review, and medication therapy management.

1 (c) "Pharmacy" shall not include any area in a facility licensed
2 by the State Department of Health Services where floor supplies,
3 ward supplies, operating room supplies, or emergency room
4 supplies of dangerous drugs or dangerous devices are stored or
5 possessed solely for treatment of patients registered for treatment
6 in the facility or for treatment of patients receiving emergency
7 care in the facility.

8 (d) "Pharmacy" shall not include a clinic licensed under
9 Section 4180 or Section 4190.

10 SEC. 3. Section 4050 of the Business and Professions Code is
11 amended to read:

12 4050. (a) In recognition of and consistent with the decisions
13 of the appellate courts of this state, the Legislature hereby
14 declares the practice of pharmacy to be a profession.

15 (b) Pharmacy practice is a dynamic patient-oriented health
16 service that applies a scientific body of knowledge to improve
17 and promote patient health by means of appropriate drug use,
18 drug-related therapy, and communication for clinical and
19 consultative purposes. *Pharmacy practice is continually evolving*
20 *to include more sophisticated and comprehensive patient care*
21 *activities.*

22 SEC. 4. Section 4051 of the Business and Professions Code is
23 amended to read:

24 4051. (a) *The holder of an unexpired and active pharmacist*
25 *license issued by the board is vested with the authority and*
26 *responsibility to perform the following functions inherent to*
27 *pharmacy practice:*

28 (1) *Interpreting, verifying, and implementing drug orders and*
29 *prescriptions.*

30 (2) *Dispensing pursuant to legitimate drug orders and*
31 *prescriptions.*

32 (3) *Ensuring proper drug storage, documentation, inventory,*
33 *labeling, and record-keeping.*

34 (4) *Maintaining accurate, complete, and confidential patient*
35 *profiles and records.*

36 (5) *Supervising pharmacy technicians and other ancillary*
37 *personnel in the pharmacy.*

38 (6) *Designing and implementing quality assurance procedures*
39 *and protocols.*

1 (7) *Compounding drug products pursuant to prescription and*
2 *for prescriber office use.*

3 (8) *Maintaining safe, secure, and sanitary conditions in*
4 *licensed premises.*

5 (9) *Performing cognitive services, including drug utilization*
6 *reviews and management, medication therapy reviews and*
7 *management, and patient counseling and consultation.*

8 (10) *Collaborating with prescribers and other health care*
9 *providers regarding patient care.*

10 (11) *Implementing standardized procedures and protocols*
11 *regarding patient care.*

12 (12) *Administering or furnishing drugs or biologicals, where*
13 *permitted by law.*

14 (13) *Initiating, adjusting, or implementing patient drug*
15 *regimens where permitted by law.*

16 (14) *Any other pharmacy functions authorized by this chapter.*

17 (b) Except as otherwise provided in this chapter, it is unlawful
18 for any person to manufacture, compound, furnish, sell, or
19 dispense any dangerous drug or dangerous device, or to dispense
20 or compound any prescription pursuant to Section 4040 of a
21 prescriber unless he or she is a pharmacist *licensed* under this
22 chapter.

23 ~~(b)~~

24 (c) *Except as otherwise provided in this chapter, it is unlawful*
25 *for any person to perform any prescription review, consultation,*
26 *drug utilization review, medication therapy management, or*
27 *other cognitive services for, pertaining to, or at the request of,*
28 *patients, prescribers, or other care providers in this state, unless*
29 *he or she is a pharmacist licensed under this chapter.*

30 (d) Notwithstanding any other law, a pharmacist *licensed*
31 *under this chapter* may authorize the initiation *or adjustment* of a
32 prescription, pursuant to Section 4052, and otherwise provide
33 *cognitive services*, clinical advice or information, or patient
34 consultation if all of the following conditions are met:

35 (1) The *cognitive service*, clinical advice, or information or
36 patient consultation is provided to a health care professional or to
37 a patient.

38 (2) The pharmacist has access to prescription *records*, patient
39 *profile profiles*, or other relevant medical information for
40 purposes of *cognitive services*, patient and clinical consultation,

1 and advice, and appropriately reviews that information before
2 performing any of these functions.

3 (3) Access to the information described in paragraph (2) is
4 secure from unauthorized access and use.

5 (4) The pharmacist authorizing initiation or adjustment of a
6 prescription, or cognitive services such as clinical advice,
7 information, or patient consultation, sets forth a complete log
8 and description of all patient records and other patient-specific
9 information, including any test results or other pertinent data,
10 used, consulted, or relied on by the pharmacist during the
11 performance of the function. The board may by regulation
12 further define the required content of the log and description.
13 This log and description shall be maintained in a readily
14 retrievable form, and provided to the board upon request, for a
15 period of at least three years from the date of performance of the
16 function. The underlying patient records and other
17 patient-specific information used, consulted, or relied on by the
18 pharmacist during the performance of the function may be
19 maintained elsewhere and not kept with the log and description,
20 as long as those records and that information are readily
21 retrievable and provided to the board upon request for a period
22 of at least three years from the date of performance of the
23 function. Otherwise, a duplicate copy of the patient records and
24 patient-specific information used, consulted or relied on shall
25 become part of the records maintained. Where the function to
26 which the log and description pertains is performed on the
27 premises of a licensed pharmacy, the obligation to keep and
28 maintain the foregoing records extends to the pharmacy and its
29 pharmacist-in-charge, and to the pharmacist performing the
30 function. Where the function to which the log and description
31 pertains is performed outside of the premises of a licensed
32 pharmacy, the obligation to keep and maintain the foregoing
33 records extends only to the performing pharmacist.

34 SEC. 5. Section 4052 of the Business and Professions Code is
35 amended to read:

36 4052. (a) Notwithstanding any other provision of law, a
37 pharmacist may:

38 (1) Furnish a reasonable quantity of compounded ~~medication~~
39 drug product to a prescriber for office use by the prescriber.

40 (2) Transmit a valid prescription to another pharmacist.

1 (3) Administer, orally or topically, drugs and biologicals
2 pursuant to a prescriber's order.

3 (4) Perform ~~the following~~ procedures or functions in a
4 licensed health care facility ~~in accordance with policies,~~
5 ~~procedures, or protocols developed by health professionals,~~
6 ~~including physicians, pharmacists, and registered nurses, with the~~
7 ~~concurrence of the facility administrator.~~

8 (A) ~~Ordering or performing routine drug therapy-related~~
9 ~~patient assessment procedures including temperature, pulse, and~~
10 ~~respiration.~~

11 (B) ~~Ordering drug therapy-related laboratory tests.~~

12 (C) ~~Administering drugs and biologicals by injection pursuant~~
13 ~~to a prescriber's order (the administration of immunizations~~
14 ~~under the supervision of a prescriber may also be performed~~
15 ~~outside of a licensed health care facility).~~

16 (D) ~~Initiating or adjusting the drug regimen of a patient~~
17 ~~pursuant to an order or authorization made by the patient's~~
18 ~~prescriber and in accordance with the policies, procedures, or~~
19 ~~protocols of the licensed health care facility. as authorized by~~
20 *Section 4052.1.*

21 (5) (A) ~~Perform the following~~ procedures or functions as part
22 of the care provided by a health care facility, a licensed home
23 health agency, a licensed clinic in which there is a physician
24 oversight, a provider who contracts with a licensed health care
25 service plan with regard to the care or services provided to the
26 enrollees of that health care service plan, or a physician, ~~in~~
27 ~~accordance, as applicable, with policies, procedures, or protocols~~
28 ~~of that facility, the home health agency, the licensed clinic, the~~
29 ~~health care service plan, or that physician, in accordance with~~
30 ~~subparagraph (C):~~

31 (i) ~~Ordering or performing routine drug therapy-related patient~~
32 ~~assessment procedures including temperature, pulse, and~~
33 ~~respiration.~~

34 (ii) ~~Ordering drug therapy-related laboratory tests.~~

35 (iii) ~~Administering drugs and biologicals by injection pursuant~~
36 ~~to a prescriber's order (the administration of immunizations~~
37 ~~under the supervision of a prescriber may also be performed~~
38 ~~outside of a licensed health care facility).~~

39 (iv) ~~Initiating or adjusting the drug regimen of a patient~~
40 ~~pursuant to a specific written order or authorization made by the~~

1 individual patient's treating prescriber, and in accordance with
2 the policies, procedures, or protocols of the health care facility,
3 home health agency, licensed clinic, health care service plan, or
4 physician. Adjusting the drug regimen does not include
5 substituting or selecting a different drug, except as authorized by
6 the protocol. The pharmacist shall provide written notification to
7 the patient's treating prescriber, or enter the appropriate
8 information in an electronic patient record system shared by the
9 prescriber, of any drug regimen initiated pursuant to this clause
10 within 24 hours.

11 (B) A patient's treating prescriber may prohibit, by written
12 instruction, any adjustment or change in the patient's drug
13 regimen by the pharmacist.

14 (C) The policies, procedures, or protocols referred to in this
15 paragraph shall be developed by health care professionals,
16 including physicians, pharmacists, and registered nurses, and, at
17 a minimum, meet all of the following requirements:

18 (i) Require that the pharmacist function as part of a
19 multidisciplinary group that includes physicians and direct care
20 registered nurses. The multidisciplinary group shall determine
21 the appropriate participation of the pharmacist and the direct care
22 registered nurse.

23 (ii) Require that the medical records of the patient be available
24 to both the patient's treating prescriber and the pharmacist.

25 (iii) Require that the procedures to be performed by the
26 pharmacist relate to a condition for which the patient has first
27 been seen by a physician.

28 (iv) Except for procedures or functions provided by a health
29 care facility, a licensed clinic in which there is physician
30 oversight, or a provider who contracts with a licensed health care
31 plan with regard to the care or services provided to the enrollees
32 of that health care service plan, require the procedures to be
33 performed in accordance with a written, patient-specific protocol
34 approved by the treating or supervising physician. Any change,
35 adjustment, or modification of an approved preexisting treatment
36 or drug therapy shall be provided in writing to the treating or
37 supervising physician within 24 hours: *as authorized by Section*
38 *4052.2.*

1 (6) Manufacture, measure, fit to the patient, or sell and repair
2 dangerous devices or furnish instructions to the patient or the
3 patient's representative concerning the use of those devices.

4 (7) Provide *cognitive services such as drug utilization review,*
5 *medication therapy management,* consultation to patients, and
6 professional information, including clinical or pharmacological
7 information, advice, or consultation to other health care
8 professionals.

9 (8) ~~(A) Furnish emergency contraception drug therapy in~~
10 ~~accordance with either of the following: as authorized by Section~~
11 ~~4052.3.~~

12 ~~(i) Standardized procedures or protocols developed by the~~
13 ~~pharmacist and an authorized prescriber who is acting within his~~
14 ~~or her scope of practice.~~

15 ~~(ii) Standardized procedures or protocols developed and~~
16 ~~approved by both the board and the Medical Board of California~~
17 ~~in consultation with the American College of Obstetricians and~~
18 ~~Gynecologists, the California Pharmacist Association, and other~~
19 ~~appropriate entities. Both the board and the Medical Board of~~
20 ~~California shall have authority to ensure compliance with this~~
21 ~~clause, and both boards are specifically charged with the~~
22 ~~enforcement of this provision with respect to their respective~~
23 ~~licensees. Nothing in this clause shall be construed to expand the~~
24 ~~authority of a pharmacist to prescribe any prescription~~
25 ~~medication.~~

26 ~~(B) Prior to performing a procedure authorized under this~~
27 ~~paragraph, a pharmacist shall complete a training program on~~
28 ~~emergency contraception that consists of at least one hour of~~
29 ~~approved continuing education on emergency contraception drug~~
30 ~~therapy.~~

31 ~~(C) A pharmacist, pharmacist's employer, or pharmacist's~~
32 ~~agent may not directly charge a patient separate consultation fee~~
33 ~~for emergency contraception drug therapy services initiated~~
34 ~~pursuant to this paragraph, but may charge an administrative fee~~
35 ~~not to exceed ten dollars (\$10) above the retail cost of the drug.~~
36 ~~Upon an oral, telephonic, electronic, or written request from a~~
37 ~~patient or customer, a pharmacist or pharmacist's employee shall~~
38 ~~disclose the total retail price that a consumer would pay for~~
39 ~~emergency contraception drug therapy. As used in this~~
40 ~~subparagraph, total retail price includes providing the consumer~~

1 with specific information regarding the price of the emergency
2 contraception drugs and the price of the administrative fee
3 charged. This limitation is not intended to interfere with other
4 contractually agreed-upon terms between a pharmacist, a
5 pharmacist's employer, or a pharmacist's agent, and a health care
6 service plan or insurer. Patients who are insured or covered and
7 receive a pharmacy benefit that covers the cost of emergency
8 contraception shall not be required to pay an administrative fee.
9 These patients shall be required to pay copayments pursuant to
10 the terms and conditions of their coverage. The provisions of this
11 subparagraph shall cease to be operative for dedicated emergency
12 contraception drugs when these drugs are reclassified as
13 over-the-counter products by the federal Food and Drug
14 Administration.

15 (D) A pharmacist may not require a patient to provide
16 individually identifiable medical information that is not specified
17 in Section 1707.1 of Title 16 of the California Code of
18 Regulations before initiating emergency contraception drug
19 therapy pursuant to this paragraph.

20 (b) (1) Prior to performing any procedure authorized by
21 paragraph (4) of subdivision (a), a pharmacist shall have received
22 appropriate training as prescribed in the policies and procedures
23 of the licensed health care facility.

24 (2) Prior to performing any procedure authorized by paragraph
25 (5) of subdivision (a), a pharmacist shall have either (A)
26 successfully completed clinical residency training or (B)
27 demonstrated clinical experience in direct patient care delivery.

28 (3) For each emergency contraception drug therapy initiated
29 pursuant to paragraph (8) of subdivision (a), the pharmacist shall
30 provide the recipient of the emergency contraception drugs with
31 a standardized factsheet that includes, but is not limited to, the
32 indications for use of the drug, the appropriate method for using
33 the drug, the need for medical followup, and other appropriate
34 information. The board shall develop this form in consultation
35 with the State Department of Health Services, the American
36 College of Obstetricians and Gynecologists, the California
37 Pharmacists Association, and other health care organizations.
38 The provisions of this section do not preclude the use of existing
39 publications developed by nationally recognized medical
40 organizations.

1 (e)
2 (9) *Administer immunizations pursuant to a protocol with a*
3 *prescriber.*

4 (b) A pharmacist who is authorized to issue an order to initiate
5 or adjust a controlled substance therapy pursuant to this section
6 shall personally register with the federal Drug Enforcement
7 Administration.

8 (d)
9 (c) Nothing in this section shall affect the requirements of
10 existing law relating to maintaining the confidentiality of medical
11 records.

12 (e)
13 (d) Nothing in this section shall affect the requirements of
14 existing law relating to the licensing of a health care facility.

15 *SEC. 6. Section 4052.1 of the Business and Professions Code*
16 *is amended and renumbered to read:*

17 ~~4052.1.~~

18 4052.4. Notwithstanding Section 2038 or any other provision
19 of law, a pharmacist may perform skin puncture in the course of
20 performing routine patient assessment procedures or in the
21 course of performing any procedure authorized under Section
22 1206.5. For purposes of this section, "routine patient assessment
23 procedures" means: (a) procedures that a patient could, with or
24 without a prescription, perform for himself or herself, or (b)
25 clinical laboratory tests that are classified as waived pursuant to
26 the federal Clinical Laboratory Improvement Amendments of
27 1988 (42 U.S.C. Sec. 263a) and the regulations adopted
28 thereunder by the federal Health Care Financing Administration,
29 as authorized by paragraph (11) of subdivision (a) of Section
30 1206.5. A pharmacist performing these functions shall report the
31 results obtained from a test to the patient and any physician
32 designated by the patient. Any pharmacist who performs the
33 service authorized by this section shall not be in violation of
34 Section 2052.

35 *SEC. 7. Section 4052.1 is added to the Business and*
36 *Professions Code, to read:*

37 4052.1. (a) *Notwithstanding any other provision of law, a*
38 *pharmacist may perform the following procedures or functions in*
39 *a licensed health care facility in accordance with policies,*
40 *procedures, or protocols developed by health professionals,*

1 including physicians, pharmacists, and registered nurses, with
2 the concurrence of the facility administrator:

3 (1) Ordering or performing routine drug therapy-related
4 patient assessment procedures including temperature, pulse, and
5 respiration.

6 (2) Ordering drug therapy-related laboratory tests.

7 (3) Administering drugs and biologicals by injection pursuant
8 to a prescriber's order.

9 (4) Initiating or adjusting the drug regimen of a patient
10 pursuant to an order or authorization made by the patient's
11 prescriber and in accordance with the policies, procedures, or
12 protocols of the licensed health care facility.

13 (b) Prior to performing any procedure authorized by this
14 section, a pharmacist shall have received appropriate training as
15 prescribed in the policies and procedures of the licensed health
16 care facility.

17 SEC. 8. Section 4052.2 is added to the Business and
18 Professions Code, to read:

19 4052.2. (a) Notwithstanding any other provision of law, a
20 pharmacist may perform the following procedures or functions
21 as part of the care provided by a health care facility, a licensed
22 home health agency, a licensed clinic in which there is a
23 physician oversight, a provider who contracts with a licensed
24 health care service plan with regard to the care or services
25 provided to the enrollees of that health care service plan, or a
26 physician, in accordance with the policies, procedures, or
27 protocols of that facility, home health agency, licensed clinic,
28 health care service plan, or physician, and in accordance with
29 subdivision (c):

30 (1) Ordering or performing routine drug therapy-related
31 patient assessment procedures including temperature, pulse, and
32 respiration.

33 (2) Ordering drug therapy-related laboratory tests.

34 (3) Administering drugs and biologicals by injection pursuant
35 to a prescriber's order.

36 (4) Initiating or adjusting the drug regimen of a patient
37 pursuant to a specific written order or authorization made by the
38 individual patient's treating prescriber, and in accordance with
39 the policies, procedures, or protocols of the health care facility,
40 home health agency, licensed clinic, health care service plan, or

1 physician. Adjusting the drug regimen does not include
2 substituting or selecting a different drug, except as authorized by
3 the protocol. The pharmacist shall provide written notification to
4 the patient's treating prescriber, or enter the appropriate
5 information in an electronic patient record system shared by the
6 prescriber, of any drug regimen initiated pursuant to this
7 paragraph within 24 hours.

8 (b) A patient's treating prescriber may prohibit, by written
9 instruction, any adjustment or change in the patient's drug
10 regimen by the pharmacist.

11 (c) The policies, procedures, or protocols referred to in this
12 subdivision shall be developed by health care professionals,
13 including physicians, pharmacists, and registered nurses, and
14 shall, at a minimum, do all of the following:

15 (1) Require that the pharmacist function as part of a
16 multidisciplinary group that includes physicians and direct care
17 registered nurses. The multidisciplinary group shall determine
18 the appropriate participation of the pharmacist and the direct
19 care registered nurse.

20 (2) Require that the medical records of the patient be
21 available to both the patient's treating prescriber and the
22 pharmacist.

23 (3) Require that the procedures to be performed by the
24 pharmacist relate to a condition for which the patient has first
25 been seen by a physician.

26 (4) Except for procedures or functions provided by a health
27 care facility, a licensed clinic in which there is physician
28 oversight, or a provider who contracts with a licensed health
29 care plan with regard to the care or services provided to the
30 enrollees of that health care service plan, require the procedures
31 to be performed in accordance with a written, patient-specific
32 protocol approved by the treating or supervising physician. Any
33 change, adjustment, or modification of an approved preexisting
34 treatment or drug therapy shall be provided in writing to the
35 treating or supervising physician within 24 hours.

36 (d) Prior to performing any procedure authorized by this
37 section, a pharmacist shall have either:

38 (1) Successfully completed clinical residency training.

39 (2) Demonstrated clinical experience in direct patient care
40 delivery.

1 *SEC. 9. Section 4052.3 is added to the Business and*
2 *Professions Code, to read:*

3 4052.3. (a) *Notwithstanding any other provision of law, a*
4 *pharmacist may furnish emergency contraception drug therapy*
5 *in accordance with either of the following:*

6 (1) *Standardized procedures or protocols developed by the*
7 *pharmacist and an authorized prescriber who is acting within his*
8 *or her scope of practice.*

9 (2) *Standardized procedures or protocols developed and*
10 *approved by both the board and the Medical Board of California*
11 *in consultation with the American College of Obstetricians and*
12 *Gynecologists, the California Pharmacist Association, and other*
13 *appropriate entities. Both the board and the Medical Board of*
14 *California shall have authority to ensure compliance with this*
15 *clause, and both boards are specifically charged with the*
16 *enforcement of this provision with respect to their respective*
17 *licensees. Nothing in this clause shall be construed to expand the*
18 *authority of a pharmacist to prescribe any prescription*
19 *medication.*

20 (b) *Prior to performing a procedure authorized under this*
21 *paragraph, a pharmacist shall complete a training program on*
22 *emergency contraception that consists of at least one hour of*
23 *approved continuing education on emergency contraception drug*
24 *therapy.*

25 (c) *A pharmacist, pharmacist's employer, or pharmacist's*
26 *agent may not directly charge a patient a separate consultation*
27 *fee for emergency contraception drug therapy services initiated*
28 *pursuant to this paragraph, but may charge an administrative fee*
29 *not to exceed ten dollars (\$10) above the retail cost of the drug.*
30 *Upon an oral, telephonic, electronic, or written request from a*
31 *patient or customer, a pharmacist or pharmacist's employee*
32 *shall disclose the total retail price that a consumer would pay for*
33 *emergency contraception drug therapy. As used in this*
34 *subparagraph, total retail price includes providing the consumer*
35 *with specific information regarding the price of the emergency*
36 *contraception drugs and the price of the administrative fee*
37 *charged. This limitation is not intended to interfere with other*
38 *contractually agreed-upon terms between a pharmacist, a*
39 *pharmacist's employer, or a pharmacist's agent, and a health*
40 *care service plan or insurer. Patients who are insured or covered*

1 and receive a pharmacy benefit that covers the cost of emergency
2 contraception shall not be required to pay an administrative fee.
3 These patients shall be required to pay copayments pursuant to
4 the terms and conditions of their coverage. The provisions of this
5 subparagraph shall cease to be operative for dedicated
6 emergency contraception drugs when these drugs are reclassified
7 as over-the-counter products by the federal Food and Drug
8 Administration.

9 (d) A pharmacist may not require a patient to provide
10 individually identifiable medical information that is not specified
11 in Section 1707.1 of Title 16 of the California Code of
12 Regulations before initiating emergency contraception drug
13 therapy pursuant to this section.

14 (e) For each emergency contraception drug therapy initiated
15 pursuant to this section, the pharmacist shall provide the
16 recipient of the emergency contraception drugs with a
17 standardized factsheet that includes, but is not limited to, the
18 indications for use of the drug, the appropriate method for using
19 the drug, the need for medical followup, and other appropriate
20 information. The board shall develop this form in consultation
21 with the State Department of Health Services, the American
22 College of Obstetricians and Gynecologists, the California
23 Pharmacists Association, and other health care organizations.
24 The provisions of this section do not preclude the use of existing
25 publications developed by nationally recognized medical
26 organizations.

27 SEC. 10. Section 4112 of the Business and Professions Code
28 is amended to read:

29 4112. (a) Any pharmacy located outside this state that ships,
30 mails, or delivers, in any manner, controlled substances,
31 dangerous drugs, or dangerous devices ~~into~~ directly to patients in
32 this state, or that performs prescription review, patient
33 consultation, drug utilization review, medication therapy
34 management, or other cognitive pharmacy services for patients
35 in this state, shall be considered a nonresident pharmacy.

36 (b) All nonresident pharmacies shall register with the board.
37 The board may register a nonresident pharmacy that is organized
38 as a limited liability company in the state in which it is licensed.

39 (c) A nonresident pharmacy shall disclose to the board the
40 location, names, and titles of (1) its agent for service of process

1 in this state, (2) all principal corporate officers, if any, *and* (3) all
2 general partners, if any, ~~and (4) all pharmacists who are~~
3 ~~dispensing controlled substances, dangerous drugs, or dangerous~~
4 ~~devices to residents of this state.~~ A report containing this
5 information shall be made on an annual basis and within 30 days
6 after any change of office, corporate officer, *or* partner, ~~or~~
7 ~~pharmacist.~~

8 (d) All nonresident pharmacies shall comply with all lawful
9 directions and requests for information from the regulatory or
10 licensing agency of the state in which it is licensed as well as
11 with all requests for information made by the board pursuant to
12 this section. The nonresident pharmacy shall maintain, at all
13 times, a valid unexpired license, permit, or registration to
14 conduct the pharmacy in compliance with the laws of the state in
15 which it is a resident. As a prerequisite to registering with the
16 board, the nonresident pharmacy shall submit a copy of the most
17 recent inspection report resulting from an inspection conducted
18 by the regulatory or licensing agency of the state in which it is
19 located.

20 (e) All nonresident pharmacies shall maintain records of
21 controlled substances, dangerous drugs, or dangerous devices
22 dispensed to patients in this state so that the records are readily
23 retrievable from the records of other drugs dispensed.

24 (f) Any pharmacy subject to this section shall, during its
25 regular hours of operation, but not less than six days per week,
26 and for a minimum of 40 hours per week, provide a toll-free
27 telephone service to facilitate communication between patients in
28 this state and a pharmacist at the pharmacy who has access to the
29 patient's records. This toll-free telephone number shall be
30 disclosed on a label affixed to each container of drugs dispensed
31 to patients in this state.

32 (g) The board shall adopt regulations that apply the same
33 requirements or standards for oral consultation to a nonresident
34 pharmacy that operates pursuant to this section and ships, mails,
35 or delivers any controlled substances, dangerous drugs, or
36 dangerous devices to residents of this state, as are applied to an
37 in-state pharmacy that operates pursuant to Section 4037 when
38 the pharmacy ships, mails, or delivers any controlled substances,
39 dangerous drugs, or dangerous devices to residents of this state.
40 The board shall not adopt any regulations that require

1 face-to-face consultation for a prescription that is shipped,
2 mailed, or delivered to the patient. The regulations adopted
3 pursuant to this subdivision shall not result in any unnecessary
4 delay in patients receiving their medication.

5 (h) The registration fee shall be the fee specified in
6 subdivision (a) of Section 4400.

7 (i) The registration requirements of this section shall apply
8 only to a nonresident pharmacy that ships, mails, or delivers
9 controlled substances, dangerous drugs, and dangerous devices
10 into this state pursuant to a prescription.

11 (j) Nothing in this section shall be construed to authorize the
12 dispensing of contact lenses by nonresident pharmacists except
13 as provided by Section 4124.

14 *SEC. 11. Section 4120 of the Business and Professions Code*
15 *is amended to read:*

16 4120. (a) ~~A nonresident pharmacy shall not sell or distribute~~
17 ~~dangerous drugs or dangerous devices in this state through any~~
18 ~~person or media other than a wholesaler who has obtained a~~
19 ~~license pursuant to this chapter or through a selling or~~
20 ~~distribution outlet that is licensed as a wholesaler pursuant to this~~
21 ~~chapter without registering as a nonresident pharmacy.~~

22 (b) ~~Applications for a nonresident pharmacy registration shall~~
23 ~~be made on a form furnished by the board. The board may~~
24 ~~require any information as the board deems reasonably necessary~~
25 ~~to carry out the purposes of this section.~~

26 (b) *Each application to conduct a nonresident pharmacy shall*
27 *specify the type or types of pharmacy for which the application is*
28 *submitted, pursuant to Section 4037. The applicant shall*
29 *immediately notify the board of any requested addition, deletion,*
30 *or other change in specified pharmacy type prior to licensure.*
31 *After licensure, any change in specified pharmacy type shall be*
32 *reported to the board, on a form to be furnished by the board, at*
33 *least 30 calendar days prior to implementation or elimination of*
34 *any activities permitted by the added, deleted, or changed type*
35 *designation.*

36 (c) The Legislature, by enacting this section, does not intend a
37 license issued to any nonresident pharmacy pursuant to this
38 section to change or affect the tax liability imposed by Chapter 3
39 (commencing with Section 23501) of Part 11 of Division 2 of the
40 Revenue and Taxation Code on any nonresident pharmacy.

1 (d) The Legislature, by enacting this section, does not intend a
2 license issued to any nonresident pharmacy pursuant to this
3 section to serve as any evidence that the nonresident pharmacy is
4 doing business within this state.

5 *SEC. 12. Section 4201 of the Business and Professions Code*
6 *is amended to read:*

7 4201. (a) Each application to conduct a pharmacy,
8 wholesaler, or veterinary food-animal drug retailer, shall be made
9 on a form furnished by the board, and shall state the name,
10 address, usual occupation, and professional qualifications, if any,
11 of the applicant. If the applicant is other than a natural person,
12 the application shall state the information as to each person
13 beneficially interested therein.

14 (b) *Each application to conduct a pharmacy shall specify the*
15 *type or types of pharmacy for which the application is submitted,*
16 *pursuant to Section 4037. The applicant shall immediately notify*
17 *the board of any requested addition, deletion, or other change in*
18 *specified pharmacy type prior to licensure. After licensure, any*
19 *change in specified pharmacy type shall be reported to the*
20 *board, on a form to be furnished by the board, at least 30*
21 *calendar days prior to implementation or elimination of any*
22 *activities permitted by the added, deleted, or changed type*
23 *designation.*

24 (c) As used in this section, and subject to subdivision (c), the
25 term “person beneficially interested” means and includes:

26 (1) If the applicant is a partnership or other unincorporated
27 association, each partner or member.

28 (2) If the applicant is a corporation, each of its officers,
29 directors, and stockholders, provided that no natural person shall
30 be deemed to be beneficially interested in a nonprofit
31 corporation.

32 (3) If the applicant is a limited liability company, each officer,
33 manager, or member.

34 ~~(e)~~

35 (d) In any case where the applicant is a partnership or other
36 unincorporated association, is a limited liability company, or is a
37 corporation, and where the number of partners, members, or
38 stockholders, as the case may be, exceeds five, the application
39 shall so state, and shall further state the information required by
40 subdivision (a) as to each of the five partners, members, or

1 stockholders who own the five largest interests in the applicant
2 entity. Upon request by the executive officer, the applicant shall
3 furnish the board with the information required by subdivision
4 (a) as to partners, members, or stockholders not named in the
5 application, or shall refer the board to an appropriate source of
6 that information.

7 ~~(d)~~

8 (e) The application shall contain a statement to the effect that
9 the applicant has not been convicted of a felony and has not
10 violated any of the provisions of this chapter. If the applicant
11 cannot make this statement, the application shall contain a
12 statement of the violation, if any, or reasons which will prevent
13 the applicant from being able to comply with the requirements
14 with respect to the statement.

15 ~~(e)~~

16 (f) Upon the approval of the application by the board and
17 payment of the fee required by this chapter for each pharmacy,
18 wholesaler, or veterinary food-animal drug retailer, the executive
19 officer of the board shall issue a license to conduct a pharmacy,
20 wholesaler, or veterinary food-animal drug retailer, if all of the
21 provisions of this chapter have been complied with.

22 ~~(f)~~

23 (g) Notwithstanding any other provision of law, the pharmacy
24 license shall authorize the holder to conduct a pharmacy. The
25 license shall be renewed annually and shall not be transferable.

26 ~~(g)~~

27 (h) Notwithstanding any other provision of law, the wholesale
28 license shall authorize the holder to wholesale dangerous drugs
29 and dangerous devices. The license shall be renewed annually
30 and shall not be transferable.

31 ~~(h)~~

32 (i) Notwithstanding any other provision of law, the veterinary
33 food-animal drug retailer license shall authorize the holder
34 thereof to conduct a veterinary food-animal drug retailer and to
35 sell and dispense veterinary food-animal drugs as defined in
36 Section 4042.

37 ~~(i)~~

38 (j) For licenses referred to in subdivisions (f), (g), and (h), any
39 change in the proposed beneficial ownership interest shall be

1 reported to the board within 30 days thereafter upon a form to be
2 furnished by the board.

3 ~~(j) This section shall become operative on July 1, 2001.~~

4 *SEC. 13. Section 4207 of the Business and Professions Code*
5 *is amended to read:*

6 4207. (a) Upon receipt of an application for a license and the
7 applicable fee, the board shall make a thorough investigation to
8 determine whether the applicant is qualified for the license being
9 sought. The board shall also determine whether this article has
10 been complied with, and shall investigate all matters directly
11 related to the issuance of the license that may affect the public
12 welfare.

13 (b) The board shall not investigate matters connected with the
14 operation of a premises other than those matters solely related to
15 the furnishing of dangerous drugs or dangerous devices, *or to the*
16 *performance or provision of prescription or drug order*
17 *processing or review services or cognitive services*, that might
18 adversely affect the public welfare.

19 (c) The board shall deny an application for a license if the
20 applicant does not qualify for the license being sought.

21 (d) Notwithstanding any other provision of law, the board may
22 request any information it deems necessary to complete the
23 application investigation required by this section, and a request
24 for information that the board deems necessary in carrying out
25 this section in any application or related form devised by the
26 board shall not be required to be adopted by regulation pursuant
27 to the ~~Administrative Procedures~~ *Procedure* Act (Chapter 3.5
28 (commencing with Section 11340) of Part 1 of Division 3 of Title
29 2 of the Government Code).

30 *SEC. 14. Section 4301 of the Business and Professions Code,*
31 *as added by Section 44 of Chapter 857 of the Statutes of 2004, is*
32 *amended to read:*

33 4301. The board shall take action against any holder of a
34 license who is guilty of unprofessional conduct or whose license
35 has been procured by fraud or misrepresentation or issued by
36 mistake. Unprofessional conduct shall include, but is not limited
37 to, any of the following:

38 (a) Gross immorality.

39 (b) Incompetence.

40 (c) Gross negligence.

1 (d) The clearly excessive furnishing of controlled substances
2 in violation of subdivision (a) of Section 11153 of the Health and
3 Safety Code.

4 (e) The clearly excessive furnishing of controlled substances
5 in violation of subdivision (a) of Section 11153.5 of the Health
6 and Safety Code. Factors to be considered in determining
7 whether the furnishing of controlled substances is clearly
8 excessive shall include, but not be limited to, the amount of
9 controlled substances furnished, the previous ordering pattern of
10 the customer (including size and frequency of orders), the type
11 and size of the customer, and where and to whom the customer
12 distributes its product.

13 (f) The commission of any act involving moral turpitude,
14 dishonesty, fraud, deceit, or corruption, whether the act is
15 committed in the course of relations as a licensee or otherwise,
16 and whether the act is a felony or misdemeanor or not.

17 (g) Knowingly making or signing any certificate or other
18 document that falsely represents the existence or nonexistence of
19 a state of facts.

20 (h) The administering to oneself, of any controlled substance,
21 or the use of any dangerous drug or of alcoholic beverages to the
22 extent or in a manner as to be dangerous or injurious to oneself,
23 to a person holding a license under this chapter, or to any other
24 person or to the public, or to the extent that the use impairs the
25 ability of the person to conduct with safety to the public the
26 practice authorized by the license.

27 (i) Except as otherwise authorized by law, knowingly selling,
28 furnishing, giving away, or administering or offering to sell,
29 furnish, give away, or administer any controlled substance to an
30 addict.

31 (j) The violation of any of the statutes of this state, *of any*
32 *other state*, or of the United States regulating controlled
33 substances and dangerous drugs.

34 (k) The conviction of more than one misdemeanor or any
35 felony involving the use, consumption, or self-administration of
36 any dangerous drug or alcoholic beverage, or any combination of
37 those substances.

38 (l) The conviction of a crime substantially related to the
39 qualifications, functions, and duties of a licensee under this
40 chapter. The record of conviction of a violation of Chapter 13

1 (commencing with Section 801) of Title 21 of the United States
2 Code regulating controlled substances or of a violation of the
3 statutes of this state regulating controlled substances or
4 dangerous drugs shall be conclusive evidence of unprofessional
5 conduct. In all other cases, the record of conviction shall be
6 conclusive evidence only of the fact that the conviction occurred.
7 The board may inquire into the circumstances surrounding the
8 commission of the crime, in order to fix the degree of discipline
9 or, in the case of a conviction not involving controlled substances
10 or dangerous drugs, to determine if the conviction is of an
11 offense substantially related to the qualifications, functions, and
12 duties of a licensee under this chapter. A plea or verdict of guilty
13 or a conviction following a plea of nolo contendere is deemed to
14 be a conviction within the meaning of this provision. The board
15 may take action when the time for appeal has elapsed, or the
16 judgment of conviction has been affirmed on appeal or when an
17 order granting probation is made suspending the imposition of
18 sentence, irrespective of a subsequent order under Section 1203.4
19 of the Penal Code allowing the person to withdraw his or her plea
20 of guilty and to enter a plea of not guilty, or setting aside the
21 verdict of guilty, or dismissing the accusation, information, or
22 indictment.

23 (m) The cash compromise of a charge of violation of Chapter
24 13 (commencing with Section 801) of Title 21 of the United
25 States Code regulating controlled substances or of Chapter 7
26 (commencing with Section 14000) of Part 3 of Division 9 of the
27 Welfare and Institutions Code relating to the Medi-Cal program.
28 The record of the compromise is conclusive evidence of
29 unprofessional conduct.

30 (n) The revocation, suspension, or other discipline by another
31 state of a license to practice pharmacy, operate a pharmacy, or do
32 any other act for which a license is required by this chapter.

33 (o) Violating or attempting to violate, directly or indirectly, or
34 assisting in or abetting the violation of or conspiring to violate
35 any provision or term of this chapter or of the applicable federal
36 and state laws and regulations governing pharmacy, including
37 regulations established by the board *or by any other state or*
38 *federal regulatory agency.*

39 (p) Actions or conduct that would have warranted denial of a
40 license.

1 (q) Engaging in any conduct that subverts or attempts to
2 subvert an investigation of the board.

3 (r) The selling, trading, transferring, or furnishing of drugs
4 obtained pursuant to Section 256b of Title 42 of the United States
5 Code to any person a licensee knows or reasonably should have
6 known, not to be a patient of a covered entity, as defined in
7 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
8 United States Code.

9 (s) The clearly excessive furnishing of dangerous drugs by a
10 wholesaler to a pharmacy that primarily or solely dispenses
11 prescription drugs to patients of long-term care facilities. Factors
12 to be considered in determining whether the furnishing of
13 dangerous drugs is clearly excessive shall include, but not be
14 limited to, the amount of dangerous drugs furnished to a
15 pharmacy that primarily or solely dispenses prescription drugs to
16 patients of long-term care facilities, the previous ordering pattern
17 of the pharmacy, and the general patient population to whom the
18 pharmacy distributes the dangerous drugs. That a wholesaler has
19 established, and employs, a tracking system that complies with
20 the requirements of subdivision (b) of Section 4164 shall be
21 considered in determining whether there has been a violation of
22 this subdivision. This provision shall not be interpreted to require
23 a wholesaler to obtain personal medical information or be
24 authorized to permit a wholesaler to have access to personal
25 medical information except as otherwise authorized by Section
26 56 and following of the Civil Code.

27 (t) This section shall become operative on January 1, 2006.

28 *SEC. 15. Section 4303 of the Business and Professions Code*
29 *is repealed.*

30 ~~4303. (a) The board may deny, revoke, or suspend a~~
31 ~~nonresident pharmacy registration for failure to comply with any~~
32 ~~requirement of Section 4112, 4124, or 4340, for any significant~~
33 ~~or repeated failure to comply with Section 4074 or 4076, or for~~
34 ~~failure to comply with Section 11164 of the Health and Safety~~
35 ~~Code.~~

36 ~~(b) The board may deny, revoke, or suspend a nonresident~~
37 ~~pharmacy registration for conduct that causes serious bodily or~~
38 ~~serious psychological injury to a resident of this state if the board~~
39 ~~has referred the matter to the regulatory or licensing agency in~~
40 ~~the state in which the pharmacy is located and the regulatory or~~

1 ~~licensing agency fails to initiate an investigation within 45 days~~
2 ~~of the referral.~~

3 SEC. 16. Section 4303 is added to the Business and
4 Professions Code, to read:

5 4303. (a) The board may report any violation of the laws and
6 regulations of this state, any other state, or of the United States,
7 including, but not limited to, any violation of this chapter or of
8 the regulations established by the board, to the appropriate
9 regulatory or licensing agency of the state in which a
10 nonresident pharmacy is a resident.

11 (b) The board may deny, revoke, or suspend a nonresident
12 pharmacy registration, issue a citation or letter of admonishment
13 to a nonresident pharmacy, or take any other action against a
14 nonresident pharmacy that the board may take against a resident
15 pharmacy license, on any of the same grounds upon such action
16 might be taken against a resident pharmacy.

17 SEC. 17. Section 4306.5 of the Business and Professions
18 Code is amended to read:

19 4306.5. (a) Unprofessional conduct for a pharmacist may
20 include ~~acts~~ any of the following:

21 (1) Acts or omissions that involve, in whole or in part, the
22 inappropriate exercise of his or her education, training, or
23 experience as a pharmacist, whether or not the act or omission
24 arises in the course of the practice of pharmacy or the ownership,
25 management, administration, or operation of a pharmacy or other
26 entity licensed by the board.

27 (2) Acts or omissions that involve, in whole or in part, the
28 failure to exercise or implement his or her best professional
29 judgment or corresponding responsibility with regard to the
30 dispensing or furnishing of controlled substances, dangerous
31 drugs, or dangerous devices or with regard to the provision of
32 cognitive services.

33 (3) Acts or omissions that involve, in whole or in part, the
34 failure to consult appropriate patient, prescription, and other
35 records pertaining to the performance of any pharmacy function.

36 (b) For pharmacists who practice outside of a pharmacy
37 premises, unprofessional conduct may include acts or omissions
38 that involve, in whole or in part, the failure to fully maintain and
39 retain appropriate patient-specific information pertaining to the
40 performance of any pharmacy function.

1 *SEC. 18. No reimbursement is required by this act pursuant*
2 *to Section 6 of Article XIII B of the California Constitution*
3 *because the only costs that may be incurred by a local agency or*
4 *school district will be incurred because this act creates a new*
5 *crime or infraction, eliminates a crime or infraction, or changes*
6 *the penalty for a crime or infraction, within the meaning of*
7 *Section 17556 of the Government Code, or changes the definition*
8 *of a crime within the meaning of Section 6 of Article XIII B of the*
9 *California Constitution.*

10
11
12 **All matter omitted in this version of the bill**
13 **appears in the bill as introduced in**
14 **Assembly, February 23, 2006 (JR11)**
15

AMENDED IN SENATE APRIL 17, 2006

SENATE BILL

No. 1475

Introduced by Senator Figueroa

February 23, 2006

An act relating to chiropractors, and declaring the urgency thereof, to take effect immediately. An act to amend Sections 28, 146, 146.5, 650.4, 2908, 4104, 4162, 4180, 4181, 4182, 4190, 4191, 4192, 4507, 4546, 4548, 4990, and 4996.26 of, to add Chapter 13.5 (commencing with Section 4987) and Chapter 13.7 (commencing with Section 4988) to Division 2 of, to repeal Sections 4990.1, 4990.2, 4990.3, 4990.5, 4990.6, 4990.7, 4990.8, 4990.9, 4990.10, 4990.11, 4990.12, 4990.125, 4990.13, 4990.14, 4990.15, 4990.16, 4992.31, 4994, and 4998.6 of, and to repeal and add Chapter 13 (commencing with Section 4980) of Division 2 of, the Business and Professions Code, to amend Section 1812.501 of the Civil Code, to amend Sections 1010, 1010.5, and 1014 of the Evidence Code, to amend Sections 6924 and 6929 of the Family Code, to amend Section 6276.18 of the Government Code, to amend Sections 1277, 1373, 1506, and 123115 of the Health and Safety Code, to amend Sections 10176 and 10177 of the Insurance Code, to amend Sections 11163.3, 11165.7, and 11174.8 of the Penal Code, and to amend Section 15610.37 of the Welfare and Institutions Code, relating to the healing arts, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1475, as amended, Figueroa. ~~Chiropractic Act: amendment by the Legislature.~~ *Healing arts.*

(1) Existing law creates the Board of Behavioral Sciences and makes it responsible for the licensure and regulation of marriage and family therapists, clinical social workers, and educational

psychologists. Under existing law, moneys received by the board are deposited into the Behavioral Sciences Fund and are continuously appropriated to the board, other than the revenue from fines and penalties. Existing law makes a violation of the provisions regulating these practitioners a crime.

This bill would recast the provisions creating the board and those that relate to the licensure and regulation of marriage and family therapists. The bill would delete the board's responsibility to review the supervision requirements for marriage and family therapist interns and trainees and obsolete provisions relating to intern registration requirements. The bill would revise the requirements for licensure as a marriage and family therapist for out-of-state licensees and for acceptance of education obtained out-of-state toward satisfying licensure requirements. The bill would name provisions regulating social workers the Clinical Social Worker Practice Act and would also establish the Educational Psychologist Practice Act that would continue the licensure and regulation of educational psychologists by the board. The bill would revise the provisions defining and regulating the practice of educational psychologists and would require licensees to complete continuing education as a prerequisite for licensure renewal. The bill would authorize the board to require those continuing education providers to pay fees to fund the administration of this requirement. Because the bill would direct their deposit into the Behavioral Sciences Fund, it would make an appropriation by increasing the amount of funds in a continuously appropriated fund. The bill would continue to make the violation of provisions regulating educational psychologists punishable as a crime and because it would prohibit the commission of additional types of conduct, the bill would expand that crime and thereby impose a state-mandated local program.

(2) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of the act a crime.

Existing law requires every pharmacy to have written policies and procedures for detecting certain impairments or drug-related acts among licensees employed by or with the pharmacy.

This bill would instead require every pharmacy to have written policies and procedures for addressing those impairments or acts by those licensees.

Existing law requires an applicant for a wholesaler license to submit a surety bond or other security to the board, as specified.

This bill would exempt a government-owned and operated wholesaler from that requirement.

Under existing law, specified clinics, including surgical clinics, may purchase drugs at wholesale for administration or dispensing to the clinic's patients. Existing law requires these clinics to maintain certain records for at least 7 years for inspection and to obtain a license from the board. Existing law specifies that each license is to be issued to a specific clinic and for a specific location. Existing law requires those clinics, when applying for a license, to show evidence that a professional director, as defined, is responsible for the provision of pharmacy services. Existing law also requires those clinics, other than surgical clinics, to retain a consulting pharmacist to perform specified tasks, including certifying in writing, at least twice a year, that the clinic is or is not operating in compliance with specified requirements, and requires the most recent certification to be submitted with the clinic's license renewal application.

This bill would instead require those clinics to maintain those records for at least 3 years and would require a separate license for each clinic location. The bill would expand the definition of "professional director" to include a dentist or podiatrist in certain circumstances. The bill would require a clinic to notify the board of any change of address, any change of the board of directors of a clinic's nonprofit corporation or, in the case of a surgical clinic, any proposed change in ownership, as specified, and any change in professional director. The bill would require surgical clinics also to retain a consulting pharmacist to perform those specified tasks. The bill would require a consulting pharmacist to provide the certification, with any recommended corrective actions, in writing quarterly and to keep the certification on file for 3 years. Because the bill would specify additional requirements under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program. The bill would make other technical changes.

(3) Existing law, the Psychiatric Technicians Law, provides for the licensure and regulation of psychiatric technicians by the Board of Vocational Nursing and Psychiatric Technicians, imposes specified fees in connection with the issuance of licenses by the board, and authorizes the board to fix certain of those fees within specified minimums and maximums. Existing law requires the board to pay all

revenue received into the State Treasury for credit to the Vocational Nursing and Psychiatric Technicians Fund. Existing law prohibits the board from maintaining a reserve balance greater than 3 months of the appropriated operating expenditures of the board in any fiscal year.

This bill would delete that prohibition and reduce the minimum amount of certain fees fixed by the board.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~The Chiropractic Act, an initiative measure approved by the voters on November 7, 1922, provides for the regulation and licensing of chiropractors in this state by the State Board of Chiropractic Examiners. Amendment of the Chiropractic Act requires approval by the voters.~~

~~This bill would declare the intent of the Legislature to enact legislation permitting the amendment of the Chiropractic Act, consistent with the intent of the act, by an extraordinary vote of the Legislature, without approval by the voters of this state.~~

~~This bill would declare that it is to take effect immediately as an urgency statute.~~

Vote: $\frac{2}{3}$ -majority. Appropriation: ~~no~~-yes. Fiscal committee: ~~no~~ yes. State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 28 of the Business and Professions Code
- 2 is amended to read:
- 3 28. The Legislature finds that there is a need to ensure that
- 4 professionals of the healing arts who have demonstrable contact
- 5 with child abuse victims, potential child abuse victims, and child
- 6 abusers and potential child abusers are provided with adequate
- 7 and appropriate training regarding the assessment and reporting
- 8 of child abuse ~~which~~ that will ameliorate, reduce, and eliminate
- 9 the trauma of child abuse and neglect and ensure the reporting of
- 10 child abuse in a timely manner to prevent additional occurrences.

1 (e) It is the intent of the Legislature in enacting this section not
2 to otherwise affect the prohibitions of Section 650. The
3 Legislature intends to allow the pooling of resources by marriage
4 and family therapists for the purpose of advertising.

5 (f) This section shall not be construed in any manner that
6 would authorize a referral service to engage in the practice of
7 marriage and family therapy.

8 *SEC. 5. Section 2908 of the Business and Professions Code is*
9 *amended to read:*

10 2908. Nothing in this chapter shall be construed to prevent
11 qualified members of other recognized professional groups
12 licensed to practice in the State of California, such as, but not
13 limited to, physicians, clinical social workers, educational
14 psychologists, marriage and family therapists, optometrists,
15 psychiatric technicians, or registered nurses, or attorneys
16 admitted to the California State Bar, or persons utilizing hypnotic
17 techniques by referral from persons licensed to practice
18 medicine, dentistry or psychology, or persons utilizing hypnotic
19 techniques—~~which~~ *that* offer avocational or vocational
20 self-improvement and do not offer therapy for emotional or
21 mental disorders, or duly ordained members of the recognized
22 clergy, or duly ordained religious practitioners from doing work
23 of a psychological nature consistent with the laws governing their
24 respective professions, provided they do not hold themselves out
25 to the public by any title or description of services incorporating
26 the words “psychological,” “psychologist,” “psychology,”
27 “psychometrist,” “psychometrics,” or “psychometry,” or that
28 they do not state or imply that they are licensed to practice
29 psychology; except that persons licensed under ~~Article 5~~
30 ~~(commencing with Section 4986) of Chapter 13 of Division 2~~
31 *Chapter 13.5 (commencing with Section 4987)* may hold
32 themselves out to the public as licensed educational
33 psychologists.

34 *SEC. 6. Section 4104 of the Business and Professions Code is*
35 *amended to read:*

36 4104. (a) Every pharmacy shall have in place procedures for
37 taking action to protect the public when a licensed individual
38 employed by or with the pharmacy is discovered or known to be
39 chemically, mentally, or physically impaired to the extent it
40 affects his or her ability to practice the profession or occupation

1 authorized by his or her license, or is discovered or known to
2 have engaged in the theft, diversion, or self-use of dangerous
3 drugs.

4 (b) Every pharmacy shall have written policies and procedures
5 for—~~detecting~~ *addressing* chemical, mental, or physical
6 impairment, as well as theft, diversion, or self-use of dangerous
7 drugs, among licensed individuals employed by or with the
8 pharmacy.

9 (c) Every pharmacy shall report to the board, within 30 days of
10 the receipt or development of the following information with
11 regard to any licensed individual employed by or with the
12 pharmacy:

13 (1) Any admission by a licensed individual of chemical,
14 mental, or physical impairment affecting his or her ability to
15 practice.

16 (2) Any admission by a licensed individual of theft, diversion,
17 or self-use of dangerous drugs.

18 (3) Any video or documentary evidence demonstrating
19 chemical, mental, or physical impairment of a licensed individual
20 to the extent it affects his or her ability to practice.

21 (4) Any video or documentary evidence demonstrating theft,
22 diversion, or self-use of dangerous drugs by a licensed
23 individual.

24 (5) Any termination based on chemical, mental, or physical
25 impairment of a licensed individual to the extent it affects his or
26 her ability to practice.

27 (6) Any termination of a licensed individual based on theft,
28 diversion, or self-use of dangerous drugs.

29 (d) Anyone participating in good faith in the making of a
30 report authorized or required by this section shall have immunity
31 from any liability, civil or criminal, that might otherwise arise
32 from the making of the report. Any participant shall have the
33 same immunity with respect to participation in any
34 administrative or judicial proceeding resulting from the report.

35 *SEC. 7. Section 4162 of the Business and Professions Code is*
36 *amended to read:*

37 4162. (a) (1) An applicant, *that is not a government-owned*
38 *and operated wholesaler*, for the issuance or renewal of a
39 wholesaler license shall submit a surety bond of one hundred
40 thousand dollars (\$100,000) or other equivalent means of

1 security acceptable to the board payable to the Pharmacy Board
2 Contingent Fund. The purpose of the surety bond is to secure
3 payment of any administrative fine imposed by the board and any
4 cost recovery ordered pursuant to Section 125.3.

5 (2) For purposes of paragraph (1), the board may accept a
6 surety bond less than one hundred thousand dollars (\$100,000) if
7 the annual gross receipts of the previous tax year for the
8 wholesaler is ten million dollars (\$10,000,000) or less, in which
9 case the surety bond shall be twenty-five thousand dollars
10 (\$25,000).

11 (3) A person to whom an approved new drug application has
12 been issued by the United States Food and Drug Administration
13 who engages in the wholesale distribution of only the dangerous
14 drug specified in the new drug application, and is licensed or
15 applies for licensure as a wholesaler, shall not be required to post
16 a surety bond as provided in paragraph (1).

17 (4) For licensees subject to paragraph (2) or (3), the board may
18 require a bond up to one hundred thousand dollars (\$100,000) for
19 any licensee who has been disciplined by any state or federal
20 agency or has been issued an administrative fine pursuant to this
21 chapter.

22 (b) The board may make a claim against the bond if the
23 licensee fails to pay a fine within 30 days after the order
24 imposing the fine, or costs become final.

25 (c) A single surety bond or other equivalent means of security
26 acceptable to the board shall satisfy the requirement of
27 subdivision (a) for all licensed sites under common control as
28 defined in Section 4126.5.

29 (d) This section shall become operative on January 1, 2006,
30 and shall remain in effect only until January 1, 2011, and as of
31 that date is repealed, unless a later enacted statute, that is enacted
32 before January 1, 2011, deletes or extends those dates.

33 *SEC. 8. Section 4180 of the Business and Professions Code is*
34 *amended to read:*

35 4180. (a) (1) Notwithstanding any provision of this chapter,
36 any of the following clinics may purchase drugs at wholesale for
37 administration or dispensing, under the direction of a physician
38 and surgeon, to patients registered for care at the clinic:

1 (A) A licensed nonprofit community clinic or free clinic as
2 defined in ~~paragraphs~~ *paragraph* (1) ~~and (2)~~ of subdivision (a) of
3 Section 1204 of the Health and Safety Code.

4 (B) A primary care clinic owned or operated by a county as
5 referred to in subdivision (b) of Section 1206 of the Health and
6 Safety Code.

7 (C) A clinic operated by a federally recognized Indian tribe or
8 tribal organization as referred to in subdivision (c) of Section
9 1206 of the Health and Safety Code.

10 (D) A clinic operated by a primary care community or free
11 clinic, operated on separate premises from a licensed clinic, and
12 that is open no more than 20 hours per week as referred to in
13 subdivision (h) of Section 1206 of the Health and Safety Code.

14 (E) A student health center clinic operated by a public
15 institution of higher education as referred to in subdivision (j) of
16 Section 1206 of the Health and Safety Code.

17 (F) A nonprofit multispecialty clinic as referred to in
18 subdivision (l) of Section 1206 of the Health and Safety Code.

19 (2) The clinic shall keep records of the kind and amounts of
20 drugs purchased, administered, and dispensed, and the records
21 shall be available and maintained for a minimum of ~~seven~~ *three*
22 years for inspection by all properly authorized personnel.

23 (b) No clinic shall be entitled to the benefits of this section
24 until it has obtained a license from the board. ~~Each license shall~~
25 ~~be issued to a specific clinic and for a specific location. A~~
26 *separate license shall be required for each clinic location. A*
27 *clinic shall notify the board of any change in the clinic's address*
28 *on a form furnished by the board.*

29 (c) *A clinic's nonprofit corporation shall report to the board*
30 *the addition or deletion of a member of the board of directors.*
31 *The report shall be submitted within 30 days of the addition or*
32 *deletion on a form furnished by the board.*

33 *SEC. 9. Section 4181 of the Business and Professions Code is*
34 *amended to read:*

35 4181. (a) Prior to the issuance of a clinic license authorized
36 under Section 4180, the clinic shall comply with all applicable
37 laws and regulations of the State Department of Health Services
38 relating to the drug distribution service to insure that inventories,
39 security procedures, training, protocol development,
40 recordkeeping, packaging, labeling, dispensing, and patient

1 consultation occur in a manner that is consistent with the
2 promotion and protection of the health and safety of the public.
3 The policies and procedures to implement the laws and
4 regulations shall be developed and approved by the consulting
5 pharmacist, the professional director, and the clinic
6 administrator.

7 ~~(b) These policies and procedures shall include a written~~
8 ~~description of the method used in developing and approving them~~
9 ~~and any revision thereof.~~

10 ~~(c)~~ The dispensing of drugs in a clinic shall be performed only
11 by a physician, a pharmacist, or other person lawfully authorized
12 to dispense drugs, and only in compliance with all applicable
13 laws and regulations.

14 *SEC. 10. Section 4182 of the Business and Professions Code*
15 *is amended to read:*

16 4182. (a) Each clinic that makes an application for a license
17 under Section 4180 shall show evidence that the professional
18 director is responsible for the safe, orderly, and lawful provision
19 of pharmacy services. In carrying out the professional director's
20 responsibilities, a consulting pharmacist shall be retained to
21 approve the policies and procedures in conjunction with the
22 professional director and the administrator. In addition, the
23 consulting pharmacist shall be required to visit the clinic
24 regularly and at least quarterly. However, nothing in this section
25 shall prohibit the consulting pharmacist from visiting more than
26 quarterly to review the application of policies and procedures
27 based on the agreement of all the parties approving the policies
28 and procedures.

29 (b) The consulting pharmacist shall certify in writing ~~at least~~
30 ~~twice a year~~ *quarterly* that the clinic is, or is not, operating in
31 compliance with the requirements of this article, ~~and the most~~
32 ~~recent of those written certifications shall be submitted with the~~
33 ~~annual application for the renewal of a clinic license.~~ *Each*
34 *completed written certification shall be kept on file in the clinic*
35 *for three years and shall include recommended corrective*
36 *actions, if appropriate.*

37 (c) For the purposes of this article, "professional director"
38 means a physician *and surgeon* acting in his or her capacity as
39 medical director *or a dentist or podiatrist acting in his or her*

1 capacity as a director in a clinic where only dental or podiatric
2 services are provided.

3 (d) Licensed clinics shall notify the board within 30 days of
4 any change in professional director on a form furnished by the
5 board.

6 SEC. 11. Section 4190 of the Business and Professions Code
7 is amended to read:

8 4190. (a) Notwithstanding any provision of this chapter, a
9 surgical clinic, as defined in paragraph (1) of subdivision (b) of
10 Section 1204 of the Health and Safety Code may purchase drugs
11 at wholesale for administration or dispensing, under the direction
12 of a physician, to patients registered for care at the clinic, as
13 provided in subdivision (b). The clinic shall keep records of the
14 kind and amounts of drugs purchased, administered, and
15 dispensed, and the records shall be available and maintained for
16 a minimum of ~~seven~~ three years for inspection by all properly
17 authorized personnel.

18 (b) The drug distribution service of a surgical clinic shall be
19 limited to the use of drugs for administration to the patients of
20 the surgical clinic and to the dispensing of drugs for the control
21 of pain and nausea for patients of the clinic. Drugs shall not be
22 dispensed in an amount greater than that required to meet the
23 patient's needs for 72 hours. Drugs for administration shall be
24 those drugs directly applied, whether by injection, inhalation,
25 ingestion, or any other means, to the body of a patient for his or
26 her immediate needs.

27 (c) No surgical clinic shall operate without a license issued by
28 the board nor shall it be entitled to the benefits of this section
29 until it has obtained a license from the board. ~~Each license shall~~
30 ~~be issued to a specific clinic and for a specific location. A~~
31 ~~separate license shall be required for each clinic location. A~~
32 ~~clinic shall notify the board of any change in the clinic's address~~
33 ~~on a form furnished by the board.~~

34 (d) Any proposed change in ownership or beneficial interest in
35 the licensee shall be reported to the board, on a form to be
36 furnished by the board, at least 30 days prior to the execution of
37 any agreement to purchase, sell, exchange, gift or otherwise
38 transfer any ownership or beneficial interest or prior to any
39 transfer of ownership or beneficial interest, whichever occurs
40 earlier.

1 *SEC. 12. Section 4191 of the Business and Professions Code*
2 *is amended to read:*

3 4191. (a) Prior to the issuance of a clinic license authorized
4 under this article, the clinic shall comply with all applicable laws
5 and regulations of the State Department of Health Services and
6 the board relating to drug distribution to insure that inventories,
7 security procedures, training, protocol development,
8 recordkeeping, packaging, labeling, dispensing, and patient
9 consultation are carried out in a manner that is consistent with the
10 promotion and protection of the health and safety of the public.
11 ~~These policies and procedures shall include a written description~~
12 ~~of the method used to develop, approve, and revise those policies~~
13 ~~and procedures. The policies and procedures to implement the~~
14 ~~laws and regulations shall be developed and approved by the~~
15 ~~consulting pharmacist, the professional director, and the clinic~~
16 ~~administrator.~~

17 (b) The dispensing of drugs in a clinic that has received a
18 license under this article shall be performed only by a physician,
19 a pharmacist, or other person lawfully authorized to dispense
20 drugs, and only in compliance with all applicable laws and
21 regulations.

22 *SEC. 13. Section 4192 of the Business and Professions Code*
23 *is amended to read:*

24 4192. (a) Each clinic that makes an application for a license
25 under this article shall show evidence that the professional
26 director is responsible for the safe, orderly, and lawful provision
27 of pharmacy services. *In carrying out the professional director's*
28 *responsibilities, a consulting pharmacist shall be retained to*
29 *approve the policies and procedures in conjunction with the*
30 *professional director and the administrator. In addition, the*
31 *consulting pharmacist shall be required to visit the clinic*
32 *regularly and at least quarterly. However, nothing in this section*
33 *shall prohibit the consulting pharmacist from visiting more than*
34 *quarterly to review the application of policies and procedures*
35 *based on the agreement of all the parties approving the policies*
36 *and procedures.*

37 (b) *The consulting pharmacist shall certify in writing quarterly*
38 *that the clinic is, or is not, operating in compliance with the*
39 *requirements of this article. Each completed written certification*

1 shall be kept on file in the clinic for three years and shall include
2 recommended corrective actions, if appropriate.

3 (c) For the purposes of this article, "professional director"
4 means a physician and surgeon acting in his or her capacity as
5 medical director or a dentist or podiatrist acting in his or her
6 capacity as a director in a clinic where only dental or podiatric
7 services are provided.

8 (d) Licensed clinics shall notify the board within 30 days of
9 any change in professional director on a form furnished by the
10 board.

11 SEC. 14. Section 4507 of the Business and Professions Code
12 is amended to read:

13 4507. This chapter shall not apply to the following:

14 (a) Physicians and surgeons licensed pursuant to Chapter 5
15 (commencing with Section 2000) of Division 2.

16 (b) Psychologists licensed pursuant to Chapter 6.6
17 (commencing with Section 2900) of Division 2.

18 (c) Registered nurses licensed pursuant to Chapter 6
19 (commencing with Section 2700) of Division 2.

20 (d) Vocational nurses licensed pursuant to Chapter 6.5
21 (commencing with Section 2840) of Division 2.

22 (e) Social workers or clinical social workers licensed pursuant
23 to Chapter 17 (commencing with Section 9000) of Division 3 14
24 (commencing with Section 4990).

25 (f) Marriage and family therapists licensed pursuant to Chapter
26 13 (commencing with Section 4980) of Division 2.

27 (g) Teachers credentialed pursuant to Chapter 1.5 2
28 (commencing with Section 13101) 44200) of Division 10 3 of the
29 Education Code.

30 (h) Occupational therapists as specified in Chapter 5.6
31 (commencing with Section 2570) of Division 2.

32 (i) Art therapists, dance therapists, music therapists, and
33 recreation therapists, as defined in Division 5 (commencing with
34 Section 70001) of Title 22 of the California Administrative Code
35 of Regulations, who are personnel of health facilities licensed
36 pursuant to Chapter 2 (commencing with Section 1250) of
37 Division 2 of the Health and Safety Code.

38 (j) Any other categories of persons the board determines are
39 entitled to exemption from this chapter because they have
40 complied with other licensing provisions of this code or because



MedImmune, Inc.

RECEIVED
CALIFORNIA BOARD OF PHARMACY
2006 MAR 21 PM 2:39

March 17, 2006

Patricia Harris
Executive Officer
California Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Harris:

I am writing to respectfully request that the Board of Pharmacy consider including in its sponsored legislation pertaining to non-resident wholesalers a clarifying amendment to California statute relating to surety bond requirements for licensed manufacturers who are also licensed as nonresident wholesalers in California. I have attached proposed language for this amendment.

Currently, as noted in the October 2005 issue of *The Script*, "[l]icensed manufacturers who are licensed as wholesalers or nonresident wholesalers in California are exempt from [surety bond] requirements." Business & Professions Code Section 4162.5(a)(4) exempts from surety bond requirements a holder of an approved new drug application, which allows for the sale and marketing of a pharmaceutical product in the United States. Our understanding is that this exemption was meant to be applied in its broadest sense to include licensed manufacturers of any pharmaceutical products considered drugs or biologics. Please note, with respect to pharmaceutical products, the FDA uses terminology particular to drugs and biologics. Specifically, manufacturers of biological products may hold a *biologics license application*, which is the equivalent of a *new drug application* for biologic products.

The attached proposed language would clarify and remove any ambiguity that the exemption to the surety bond requirement for licensed manufacturers that are also licensed as nonresident wholesalers applies to manufacturers with approved new drug applications and approved biologics license applications.

I very much appreciate your consideration of this request. Please feel free to contact me at (510) 339-1693 if I can answer any questions or if you would like to discuss this further.

Sincerely,

Colleen Chawla
Government Affairs Manager

Enclosure

MedImmune Legislative Proposal Request

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or a biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

AMENDED IN SENATE APRIL 17, 2006

SENATE BILL

No. 1476

Introduced by Senator Figueroa

February 23, 2006

An act to amend Sections ~~2570.19 and 2602~~ of 1601.1, 1742, 2460, 2570.4, 2570.19, 2602, 2668, 2701, 2708, 2920, 2933, 3010.5, 3014.6, 3504, 3512, 3516.1, 3685, 3710, 3716, 4001, 4003, 4034, 4163, 4169, 4800, 4804.5, 4928, 4934, 4990.1, 5510, 5517, 5620, 5621, 5622, 6710, 6714, 7200, 7215.6, 7810, 7815.5, and 8000 of, to add Section 2660.5 to, and to repeal Section 4163.5 of, the Business and Professions Code, relating to ~~healing arts~~ professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1476, as amended, Figueroa. Professions and vocations.

(1) Existing law, the Dental Practice Act, provides for the licensing and regulation of dentists by the Dental Board of California and for the licensing and regulation of dental auxiliaries by the Committee on Dental Auxiliaries. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(2) Existing law provides for the licensing and regulation of podiatrists by the California Board of Podiatric Medicine, within the jurisdiction of the Medical Board of California. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead makes these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

(3) Existing law, *the Occupational Therapy Practice Act*, provides for the licensing and regulation of occupational therapists *and the certification and regulation of occupational therapy assistants* by the California Board of Occupational Therapy. These provisions will become inoperative on July 1, 2007, and will be repealed on January 1, 2008.

This bill would instead make these provisions inoperative on *July 1, 2013*, and would repeal them on ~~unspecified dates~~ *January 1, 2014*.

(2)

Existing law exempts certain persons from the requirements of the act, including a licensee from a state with commensurately stringent requirements, if the services are performed for less than 45 days in a calender year and are performed in association with an occupational therapist licensed under the act.

This bill would instead require a licensee from a state with commensurately stringent requirements to have filed with the board an application for licensure as an occupational therapist or certified occupational therapy assistant and would require that his or her services be performed for no more than 60 days from the date on which the application is filed. The bill would delete the requirement that the services be performed in association with an occupational therapist licensed in the state.

(4) Existing law provides for the licensure and regulation of physical therapists and physical ~~therapy~~ therapist assistants by the Physical Therapy Board of California. These provisions will become inoperative on July 1, 2007, and will be repealed on January 1, 2008.

This bill would instead make these provisions inoperative on *July 1, 2013*, and would repeal them on ~~unspecified dates~~ *January 1, 2014*.

Existing law provides for a diversion program for the rehabilitation of physical therapists and physical therapist assistants abusing drugs or alcohol, and authorizes the board to charge a fee of up to \$100 for participation in the program. Existing law requires persons convicted of certain sex offenses to register as sex offenders, as specified.

This bill would change the fee for participation in the diversion program to the amount necessary to cover the actual cost of administering the program. Because this bill could increase the fee revenue deposited into the Physical Therapy Fund, a continuously appropriated fund, the bill would make an appropriation. The bill would also require the board to deny licensure as a physical therapist or approval as a physical therapist assistant if the applicant is

required to register as a sex offender, unless the registration is required as a result of a misdemeanor conviction for indecent exposure.

(5) Existing law provides for the licensure and regulation of registered nurses by the Board of Registered Nursing, in the Department of Consumer Affairs, and requires the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

(6) Existing law provides for the licensing and regulation of psychologists by the Board of Psychology. Existing law requires the board to employ necessary personnel, and authorizes the board to employ an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(7) Existing law provides for the licensure and regulation of optometrists by the State Board of Optometry, in the Department of Consumer Affairs, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

(8) Existing law provides for the licensure and regulation of physician assistants by the Physician Assistant Committee of the Medical Board of California. Existing law requires the committee to employ necessary personnel, including an executive officer. Existing law prohibits a physician who provides services in a medically underserved area from supervising more than 4 physician assistants at one time. All of these provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2011, and would repeal them on January 1, 2012.

(9) Existing law, The Naturopathic Doctors Act, provides for the licensure and regulation of the practice of naturopathic medicine, and establishes the Bureau of Naturopathic Medicine, in the Department of Consumer Affairs, which is responsible for the administration of the act. A violation of certain provisions of the act is a crime. The act will

become inoperative on July 1, 2009, and will be repealed on January 1, 2010.

This bill would instead make the act inoperative on July 1, 2010, and would repeal it on January 1, 2011.

Because this bill would extend the application of certain provisions, the violation of which would be a crime, it would impose a state-mandated local program.

(10) Existing law provides for the licensure and regulation of respiratory professionals by the Respiratory Care Board of California, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

(11) Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2010, and would repeal them on January 1, 2011.

On and after January 1, 2007, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree, as defined, and prohibits a wholesaler or pharmacy from acquiring a dangerous drug without receiving a pedigree, unless the compliance date is extended. Existing law authorizes the board to extend the compliance date to January 1, 2008, in specified circumstances.

This bill would instead impose the prohibition against selling, trading, transferring, or acquiring a dangerous drug without a pedigree on January 1, 2008, and would make other conforming changes.

(12) Existing law provides for the licensure and regulation of veterinarians by the Veterinary Medical Board in the Department of Consumer Affairs, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2009, and will be repealed on January 1, 2010.

This bill would instead make these provisions inoperative on July 1, 2011, and would repeal them on January 1, 2012.

(13) Existing law provides for the licensure and regulation of acupuncturists by the Acupuncture Board and requires the board to employ necessary personnel, including an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(14) Existing law provides for the licensure and regulation of the practice of behavioral health by the Board of Behavioral Sciences, in the Department of Consumer Affairs, and authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will repeal them on January 1, 2009.

This bill would instead makes these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(15) Existing law provides for the licensure and regulation of architects by the California Architects Board, and provides for the creation of the Landscape Architects Technical Committee to assist the board with specified functions. Existing law authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2009, and will be repealed on January 1, 2010.

This bill would instead make these provisions inoperative on July 1, 2011, and would repeal them on January 1, 2012.

(16) Existing law provides for the licensure and regulation of professional engineers and land surveyors by the Board for Professional Engineers and Land Surveyors, in the Department of Consumer Affairs. Existing law requires the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2011, and would repeal them on January 1, 2012.

(17) Existing law establishes within the Department of Consumer Affairs a State Board of Guide Dogs for the Blind, which licenses schools for the training of guide dogs for the blind. Existing law also establishes a pilot project for the arbitration of disputes between guide dog users and guide schools relating to the continued physical custody and use of the guide dog when the dog user is not the legal owner of the dog. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2011, and would repeal them on January 1, 2012.

(18) Existing law provides for the licensure and regulation of geologists and geophysicists by the Board for Geologists and Geophysicists, subject to the jurisdiction of the Department of Consumer Affairs. Existing law authorizes the board to appoint an executive officer. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(19) Existing law provides for the licensure and regulation of court reporters by the Court Reporters Board of California, in the Department of Consumer Affairs. These provisions will become inoperative on July 1, 2008, and will be repealed on January 1, 2009.

This bill would instead make these provisions inoperative on July 1, 2009, and would repeal them on January 1, 2010.

(20) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~no~~-yes. Fiscal committee: yes. State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1601.1 of the Business and Professions
2 Code is amended to read:
3 1601.1. (a) There shall be in the Department of Consumer
4 Affairs the Dental Board of California in which the
5 administration of this chapter is vested. The board shall consist of
6 eight practicing dentists, one registered dental hygienist, one
7 registered dental assistant, and four public members. Of the eight
8 practicing dentists, one shall be a member of a faculty of any
9 California dental college and one shall be a dentist practicing in a
10 nonprofit community clinic. The appointing powers, described in
11 Section 1603, may appoint to the board a person who was a
12 member of the prior board. The board shall be organized into

1 *SEC. 19. Section 3710 of the Business and Professions Code*
2 *is amended to read:*

3 3710. The Respiratory Care Board of California, hereafter
4 referred to as the board, shall enforce and administer this chapter.

5 This section shall become inoperative on July 1, ~~2008~~ 2010,
6 and, as of January 1, ~~2009~~ 2011, is repealed, unless a later
7 enacted statute, that becomes operative on or before January 1,
8 ~~2009~~ 2011, deletes or extends the dates on which it becomes
9 inoperative and is repealed.

10 The repeal of this section renders the board subject to the
11 review required by Division 1.2 (commencing with Section 473).

12 *SEC. 20. Section 3716 of the Business and Professions Code*
13 *is amended to read:*

14 3716. The board may employ an executive officer exempt
15 from civil service and, subject to the provisions of law relating to
16 civil service, clerical assistants and, except as provided in Section
17 159.5, other employees as it may deem necessary to carry out its
18 powers and duties.

19 This section shall become inoperative on July 1, ~~2008~~ 2010,
20 and, as of January 1, ~~2009~~ 2011, is repealed, unless a later
21 enacted statute, that becomes operative on or before January 1,
22 ~~2009~~ 2011, deletes or extends the dates on which it becomes
23 inoperative and is repealed.

24 *SEC. 21. Section 4001 of the Business and Professions Code*
25 *is amended to read:*

26 4001. (a) There is in the Department of Consumer Affairs a
27 California State Board of Pharmacy in which the administration
28 and enforcement of this chapter is vested. The board consists of
29 13 members.

30 (b) The Governor shall appoint seven competent pharmacists
31 who reside in different parts of the state to serve as members of
32 the board. The Governor shall appoint four public members, and
33 the Senate Committee on Rules and the Speaker of the Assembly
34 shall each appoint a public member who shall not be a licensee of
35 the board, any other board under this division, or any board
36 referred to in Section 1000 or 3600.

37 (c) At least five of the seven pharmacist appointees to the
38 board shall be pharmacists who are actively engaged in the
39 practice of pharmacy. Additionally, the membership of the board
40 shall include at least one pharmacist representative from each of

1 the following practice settings: an acute care hospital, an
2 independent community pharmacy, a chain community
3 pharmacy, and a long-term health care or skilled nursing facility.
4 The pharmacist appointees shall also include a pharmacist who is
5 a member of a labor union that represents pharmacists. For the
6 purposes of this subdivision, a “chain community pharmacy”
7 means a chain of 75 or more stores in California under the same
8 ownership, and an “independent community pharmacy” means a
9 pharmacy owned by a person or entity who owns no more than
10 four pharmacies in California.

11 (d) Members of the board shall be appointed for a term of four
12 years. No person shall serve as a member of the board for more
13 than two consecutive terms. Each member shall hold office until
14 the appointment and qualification of his or her successor or until
15 one year shall have elapsed since the expiration of the term for
16 which the member was appointed, whichever first occurs.
17 Vacancies occurring shall be filled by appointment for the
18 unexpired term.

19 (e) Each member of the board shall receive a per diem and
20 expenses as provided in Section 103.

21 (f) In accordance with Sections 101.1 and 473.1, this section
22 shall become inoperative on July 1, ~~2008~~ 2010, and, as of
23 January 1, ~~2009~~ 2011, is repealed, unless a later enacted statute,
24 that becomes effective on or before January 1, ~~2009~~ 2011, deletes
25 or extends the dates on which it becomes inoperative and is
26 repealed. The repeal of this section renders the board subject to
27 the review required by Division 1.2 (commencing with Section
28 473).

29 *SEC. 22. Section 4003 of the Business and Professions Code*
30 *is amended to read:*

31 4003. (a) The board may appoint a person exempt from civil
32 service who shall be designated as an executive officer and who
33 shall exercise the powers and perform the duties delegated by the
34 board and vested in him or her by this chapter. The executive
35 officer may or may not be a member of the board as the board
36 may determine.

37 (b) The executive officer shall receive the compensation as
38 established by the board with the approval of the Director of
39 Finance. The executive officer shall also be entitled to travel and
40 other expenses necessary in the performance of his or her duties.

1 (c) The executive officer shall maintain and update in a timely
2 fashion records containing the names, titles, qualifications, and
3 places of business of all persons subject to this chapter.

4 (d) The executive officer shall give receipts for all money
5 received by him or her and pay it to the Department of Consumer
6 Affairs, taking its receipt therefor. Besides the duties required by
7 this chapter, the executive officer shall perform other duties
8 pertaining to the office as may be required of him or her by the
9 board.

10 (e) In accordance with Sections 101.1 and 473.1, this section
11 shall become inoperative on July 1, ~~2008~~ 2010, and, as of
12 January 1, ~~2009~~ 2011, is repealed, unless a later enacted statute,
13 that becomes effective on or before January 1, ~~2009~~ 2011, deletes
14 or extends the dates on which it becomes inoperative and is
15 repealed.

16 *SEC. 21. Section 4034 of the Business and Professions Code*
17 *is amended to read:*

18 4034. (a) "Pedigree" means a record, in electronic form,
19 containing information regarding each transaction resulting in a
20 change of ownership of a given dangerous drug, from sale by a
21 manufacturer, through acquisition and sale by a wholesaler, until
22 final sale to a pharmacy or other person furnishing,
23 administering, or dispensing the dangerous drug.

24 (b) A pedigree shall include all of the following information:

25 (1) The source of the dangerous drug, including the name,
26 state license number, including California license number if
27 available, and principal address of the source.

28 (2) The quantity of the dangerous drug, its dosage form and
29 strength, the date of the transaction, the sales invoice number, the
30 container size, the number of containers, the expiration dates, and
31 the lot numbers.

32 (3) The business name, address, and if appropriate, the state
33 license number, including a California license number if
34 available, of each owner of the dangerous drug, and the
35 dangerous drug shipping information, including the name and
36 address of each person certifying delivery or receipt of the
37 dangerous drug.

38 (4) A certification under penalty of perjury from a responsible
39 party of the source of the dangerous drug that the information
40 contained in the pedigree is true and accurate.

1 (c) If a licensed health care service plan, hospital organization,
2 and one or more physician organizations have exclusive
3 contractual relationships to provide health care services, drugs
4 distributed between these persons shall be deemed not to have
5 changed ownership.

6 (d) The application of the pedigree requirement in pharmacies
7 shall be subject to review during the board's sunset review to be
8 conducted as described in subdivision (f) of Section 4001.

9 (e) This section shall become operative on January 1, ~~2007~~
10 2008.

11 *SEC. 22. Section 4163 of the Business and Professions Code,*
12 *as amended by Section 31 of Chapter 857 of the Statutes of 2004,*
13 *is amended to read:*

14 4163. (a) No manufacturer or wholesaler shall furnish any
15 dangerous drugs or dangerous devices to any unauthorized
16 persons.

17 (b) No person shall acquire dangerous drugs or dangerous
18 devices from a person not authorized by law to possess or furnish
19 those dangerous drugs or dangerous devices. When the person
20 acquiring the dangerous drugs or dangerous devices is a
21 wholesaler, the obligation of the wholesaler shall be limited to
22 obtaining confirmation of licensure of those sources from whom
23 it has not previously acquired dangerous drugs or dangerous
24 devices.

25 (c) This section shall remain in effect only until January 1,
26 ~~2007~~ 2008, and as of that date is repealed, unless a later enacted
27 statute, that is enacted before January 1, ~~2007~~ 2008, deletes or
28 extends that date.

29 *SEC. 23. Section 4163 of the Business and Professions Code,*
30 *as added by Section 32 of Chapter 857 of the Statutes of 2004, is*
31 *amended to read:*

32 4163. (a) A manufacturer or wholesaler may not furnish a
33 dangerous drug or dangerous device to an unauthorized person.

34 (b) Dangerous drugs or dangerous devices shall be acquired
35 from a person authorized by law to possess or furnish dangerous
36 drugs or dangerous devices. When the person acquiring the
37 dangerous drugs or dangerous devices is a wholesaler, the
38 obligation of the wholesaler shall be limited to obtaining
39 confirmation of licensure of those sources from whom it has not
40 previously acquired dangerous drugs or dangerous devices.

1 (c) A wholesaler or pharmacy may not sell, trade, or transfer a
2 dangerous drug at wholesale without providing a pedigree.

3 (d) A wholesaler or pharmacy may not acquire a dangerous
4 drug without receiving a pedigree.

5 (e) This section shall become operative on January 1, ~~2007~~
6 ~~2008~~.

7 *SEC. 24. Section 4163.5 of the Business and Professions*
8 *Code is repealed.*

9 ~~4163.5. The board may extend the date for compliance with~~
10 ~~the requirement for a pedigree set forth in Section 4163 until~~
11 ~~January 1, 2008, if it determines that manufacturers or~~
12 ~~wholesalers require additional time to implement electronic~~
13 ~~technologies to track the distribution of dangerous drugs within~~
14 ~~the state. A determination by the board to extend the deadline for~~
15 ~~providing pedigrees shall not be subject to the requirements of~~
16 ~~Chapter 3.5 (commencing with Section 11340) of Part 1 of~~
17 ~~Division 3 of Title 2 of the Government Code.~~

18 *SEC. 25. Section 4169 of the Business and Professions Code,*
19 *as added by Section 39 of Chapter 857 of the Statutes of 2004, is*
20 *amended to read:*

21 4169. (a) A person or entity may not do any of the following:

22 (1) Purchase, trade, sell, or transfer dangerous drugs or
23 dangerous devices at wholesale with a person or entity that is not
24 licensed with the board as a wholesaler or pharmacy, in violation
25 of Section 4163.

26 (2) Purchase, trade, sell, or transfer dangerous drugs that the
27 person knew or reasonably should have known were adulterated,
28 as set forth in Article 2 (commencing with Section 111250) of
29 Chapter 6 of Part 5 of Division 104 of the Health and Safety
30 Code.

31 (3) Purchase, trade, sell, or transfer dangerous drugs that the
32 person knew or reasonably should have known were misbranded,
33 as defined in Section 111335 of the Health and Safety Code.

34 (4) Purchase, trade, sell, or transfer dangerous drugs or
35 dangerous devices after the beyond use date on the label.

36 (5) Fail to maintain records of the acquisition or disposition of
37 dangerous drugs or dangerous devices for at least three years.

38 (b) Notwithstanding any other provision of law, a violation of
39 this section may subject the person or entity that has committed
40 the violation to a fine not to exceed the amount specified in

1 Section 125.9 for each occurrence, pursuant to a citation issued
2 by the board.

3 (c) Amounts due from any person under this section shall be
4 offset as provided under Section 12419.5 of the Government
5 Code. Amounts received by the board under this section shall be
6 deposited into the Pharmacy Board Contingent Fund.

7 (d) This section shall not apply to a pharmaceutical
8 manufacturer licensed by the Food and Drug Administration or
9 by the State Department of Health Services.

10 (e) This section shall remain in effect only until January 1,
11 ~~2007~~ 2008, and as of that date is repealed, unless a later enacted
12 statute, that is enacted before January 1, ~~2007~~ 2008, deletes or
13 extends that date.

14 *SEC. 26. Section 4169 of the Business and Professions Code,*
15 *as added by Section 40 of Chapter 857 of the Statutes of 2004, is*
16 *amended to read:*

17 4169. (a) A person or entity may not do any of the following:

18 (1) Purchase, trade, sell, or transfer dangerous drugs or
19 dangerous devices at wholesale with a person or entity that is not
20 licensed with the board as a wholesaler or pharmacy.

21 (2) Purchase, trade, sell, or transfer dangerous drugs that the
22 person knew or reasonably should have known were adulterated,
23 as set forth in Article 2 (commencing with Section 111250) of
24 Chapter 6 of Part 5 of Division 104 of the Health and Safety
25 Code.

26 (3) Purchase, trade, sell, or transfer dangerous drugs that the
27 person knew or reasonably should have known were misbranded,
28 as defined in Section 111335 of the Health and Safety Code.

29 (4) Purchase, trade, sell, or transfer dangerous drugs or
30 dangerous devices after the beyond use date on the label.

31 (5) Fail to maintain records of the acquisition or disposition of
32 dangerous drugs or dangerous devices for at least three years.

33 (b) Notwithstanding any other provision of law, a violation of
34 this section or of subdivision (c) or (d) of Section 4163 may
35 subject the person or entity that has committed the violation to a
36 fine not to exceed the amount specified in Section 125.9 for each
37 occurrence, pursuant to a citation issued by the board.

38 (c) Amounts due from any person under this section shall be
39 offset as provided under Section 12419.5 of the Government

1 Code. Amounts received by the board under this section shall be
2 deposited into the Pharmacy Board Contingent Fund.

3 (d) This section shall not apply to a pharmaceutical
4 manufacturer licensed by the Food and Drug Administration or
5 by the State Department of Health Services.

6 (e) This section shall become operative on January 1, ~~2007~~
7 2008.

8 *SEC. 27. Section 4800 of the Business and Professions Code*
9 *is amended to read:*

10 4800. There is in the Department of Consumer Affairs a
11 Veterinary Medical Board in which the administration of this
12 chapter is vested. The board consists of seven members, three of
13 whom shall be public members.

14 This section shall become inoperative on July 1, ~~2009~~ 2011,
15 and, as of January 1, ~~2010~~ 2012, is repealed, unless a later
16 enacted statute, which becomes effective on or before January 1,
17 2010 2012, deletes or extends the dates on which it becomes
18 inoperative and is repealed.

19 The repeal of this section renders the board subject to the
20 review provided for by Division 1.2 (commencing with Section
21 473).

22 *SEC. 28. Section 4804.5 of the Business and Professions*
23 *Code is amended to read:*

24 4804.5. The board may appoint a person exempt from civil
25 service who shall be designated as an executive officer and who
26 shall exercise the powers and perform the duties delegated by the
27 board and vested in him or her by this chapter.

28 This section shall become inoperative on July 1, ~~2009~~ 2011,
29 and, as of January 1, ~~2010~~ 2012, is repealed, unless a later
30 enacted statute, which becomes effective on or before January 1,
31 2010 2012, deletes or extends the dates on which it becomes
32 inoperative and is repealed.

33 *SEC. 29. Section 4928 of the Business and Professions Code*
34 *is amended to read:*

35 4928. The Acupuncture Board, which consists of seven
36 members, shall enforce and administer this chapter. The
37 appointing powers, as described in Section 4929, may appoint to
38 the board a person who was a member of the prior board prior to
39 the repeal of that board on January 1, 2006.

Blank